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Schmidt et al.

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(54) **LEADLESS CARDIAC PACEMAKER WITH DELIVERY AND/OR RETRIEVAL FEATURES**

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(52) **U.S. Cl.**

CPC *A61N 1/3756* (2013.01); *A61N 1/362* (2013.01); *A61N 1/37205* (2013.01)

(58) **Field of Classification Search**

CPC *A61N 1/3756*; *A61N 1/37205*; *A61N 1/362*; *A61N 2001/0578*; *A61N 1/0573*;

A61N 1/059; *A61N 1/372*; *A61N 2001/058*;
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A61B 2017/22035; *A61B 17/221*; *A61B 5/686*; *A61F 2002/011*; *A61F 2/2427*
USPC 600/373; 606/128, 129, 200, 108;
607/122, 126, 127, 128; 623/1.11
See application file for complete search history.

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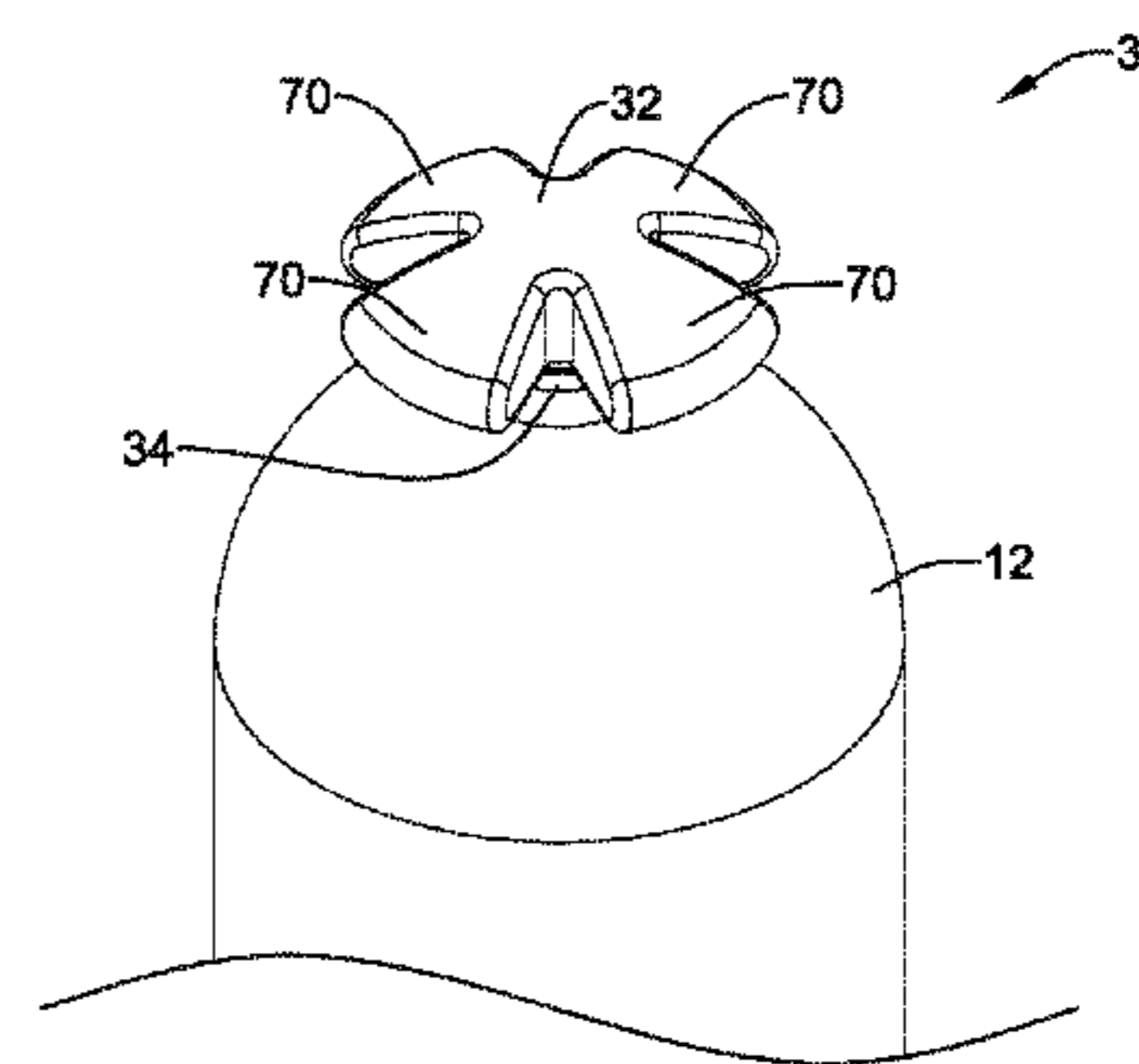
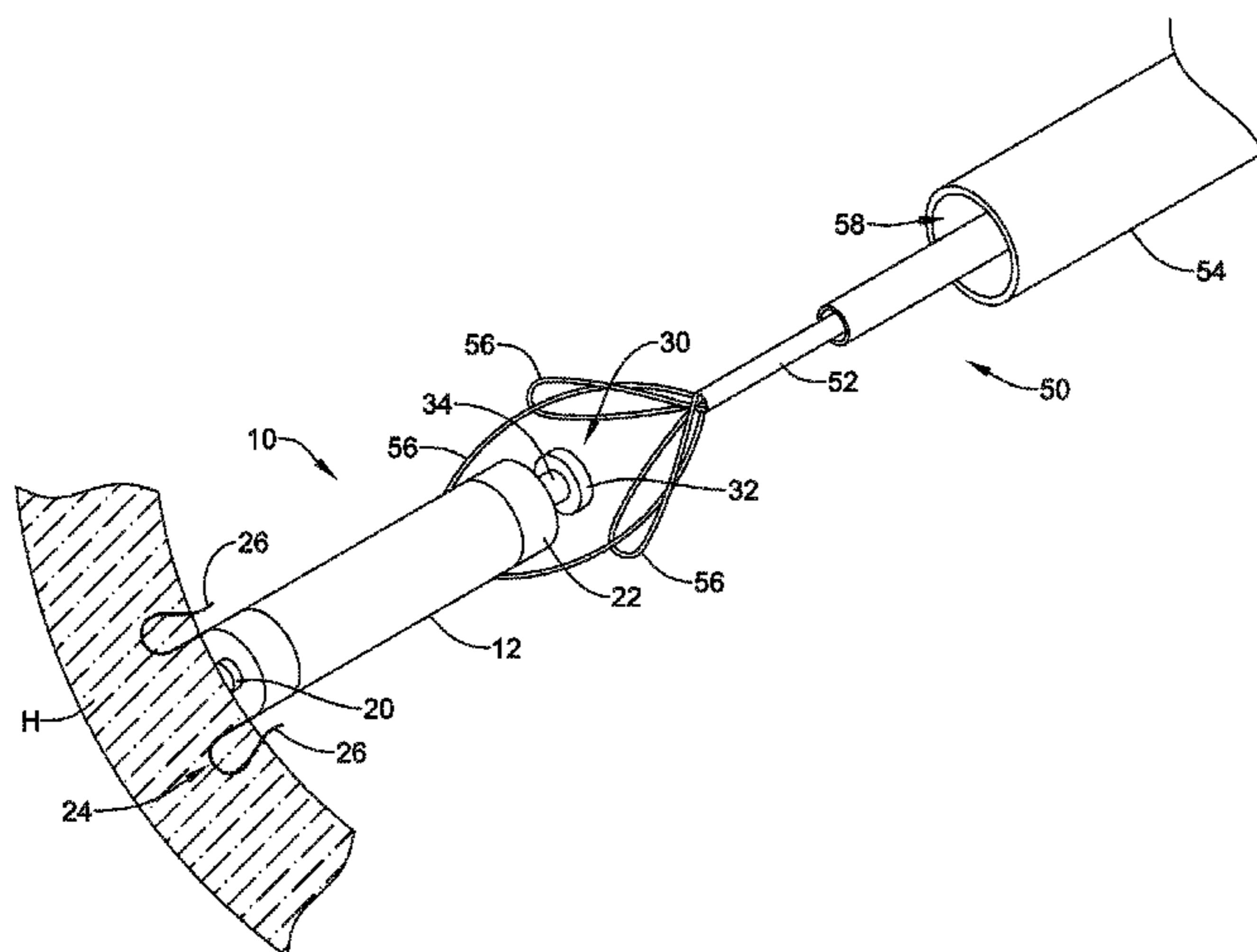
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(57) **ABSTRACT**

An implantable leadless cardiac pacing device and associated delivery and retrieval devices. The implantable device includes a docking member extending from the proximal end of the housing of the implantable device configured to engage with the delivery and/or retrieval device to facilitate delivery and/or retrieval of the implantable leadless cardiac pacing device.

12 Claims, 49 Drawing Sheets



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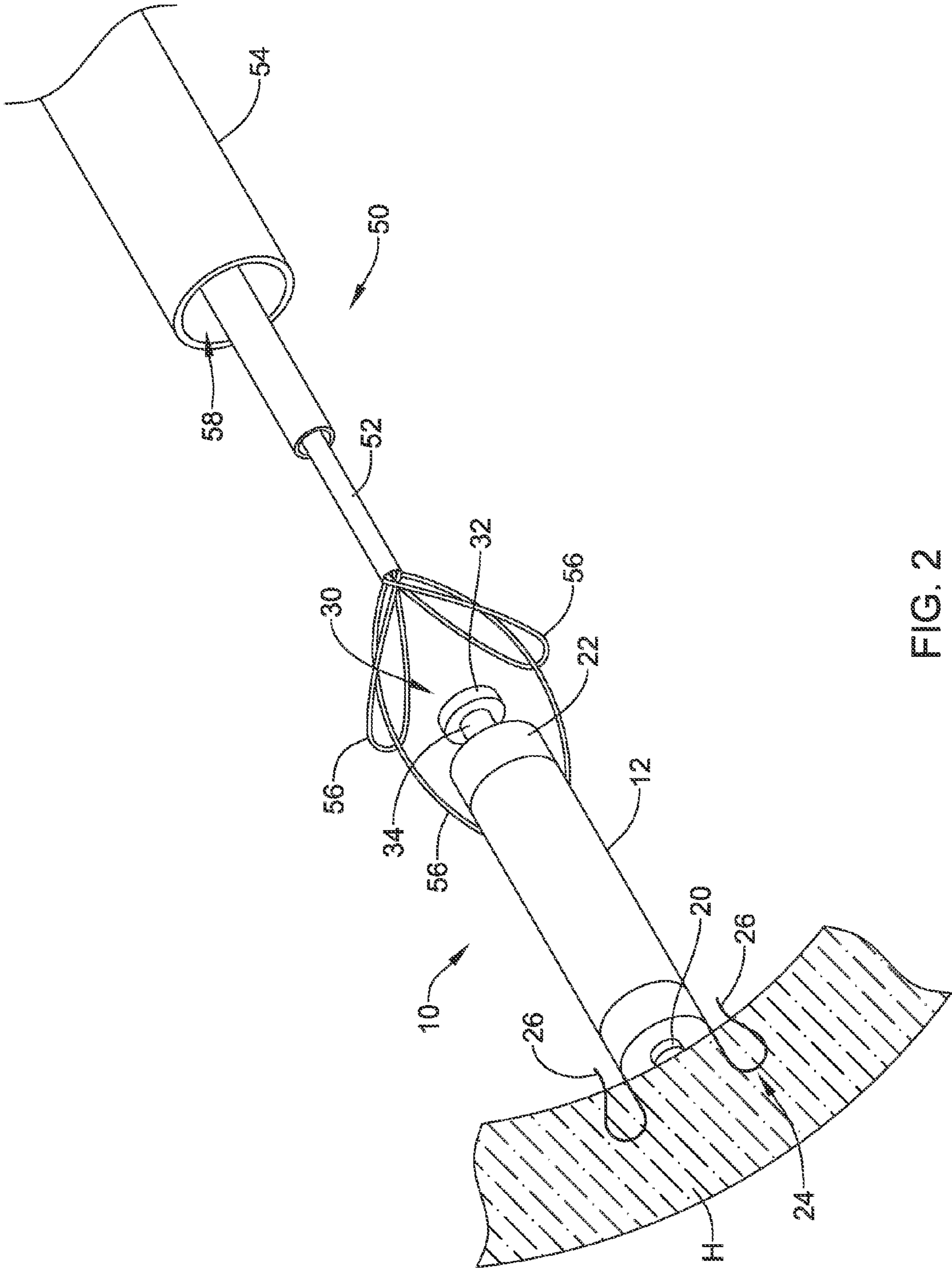


FIG. 2

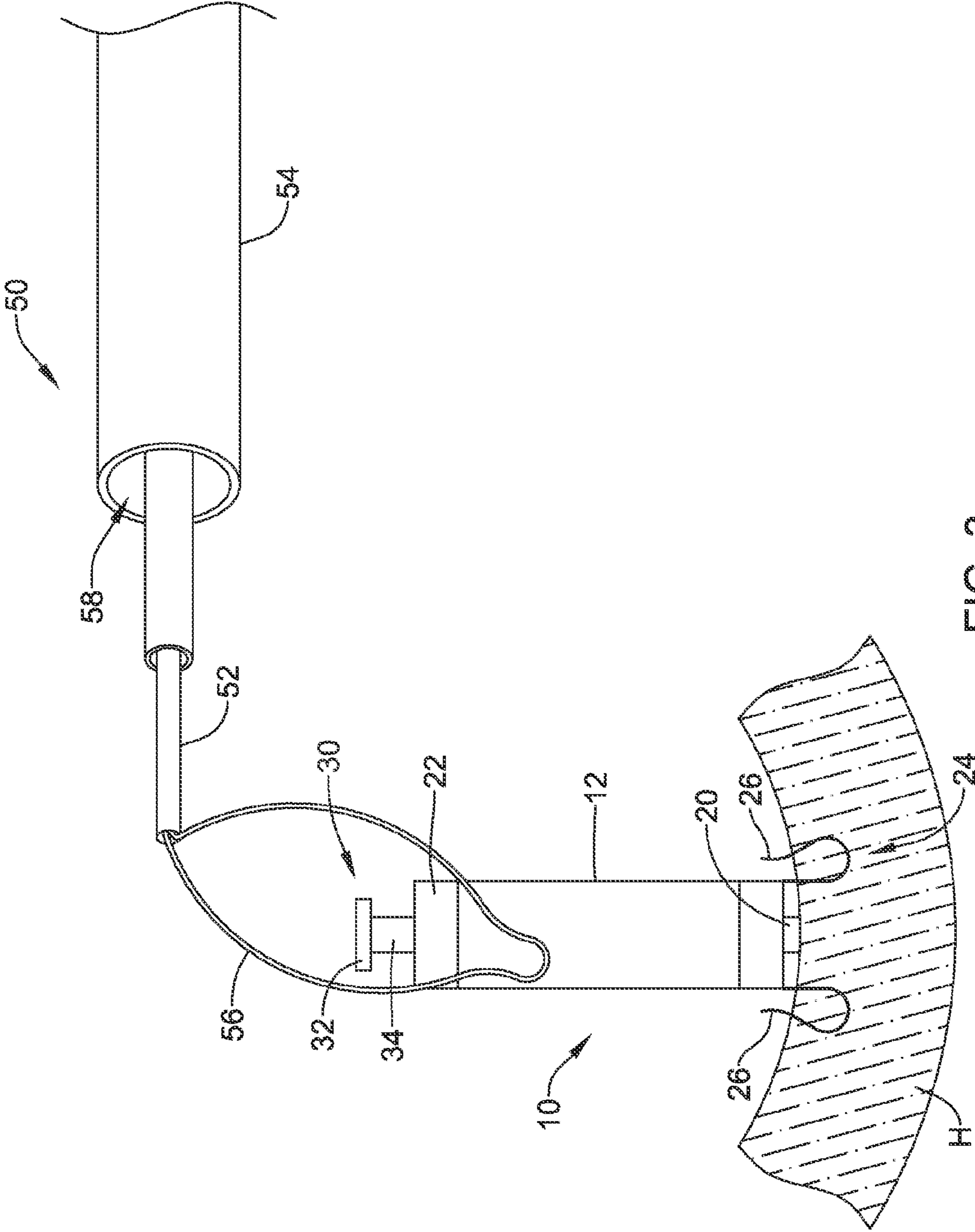


FIG. 3

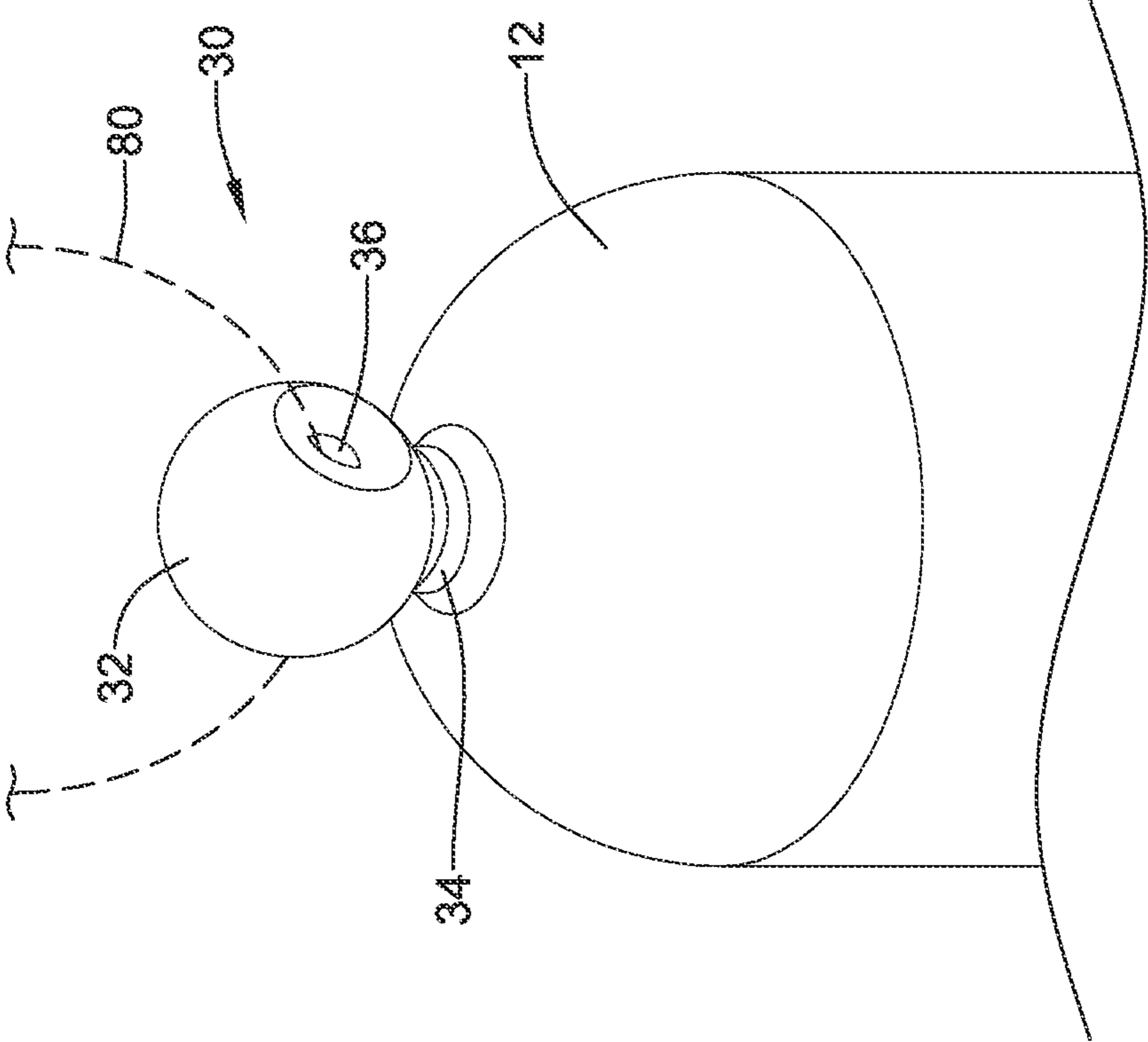


FIG. 4A

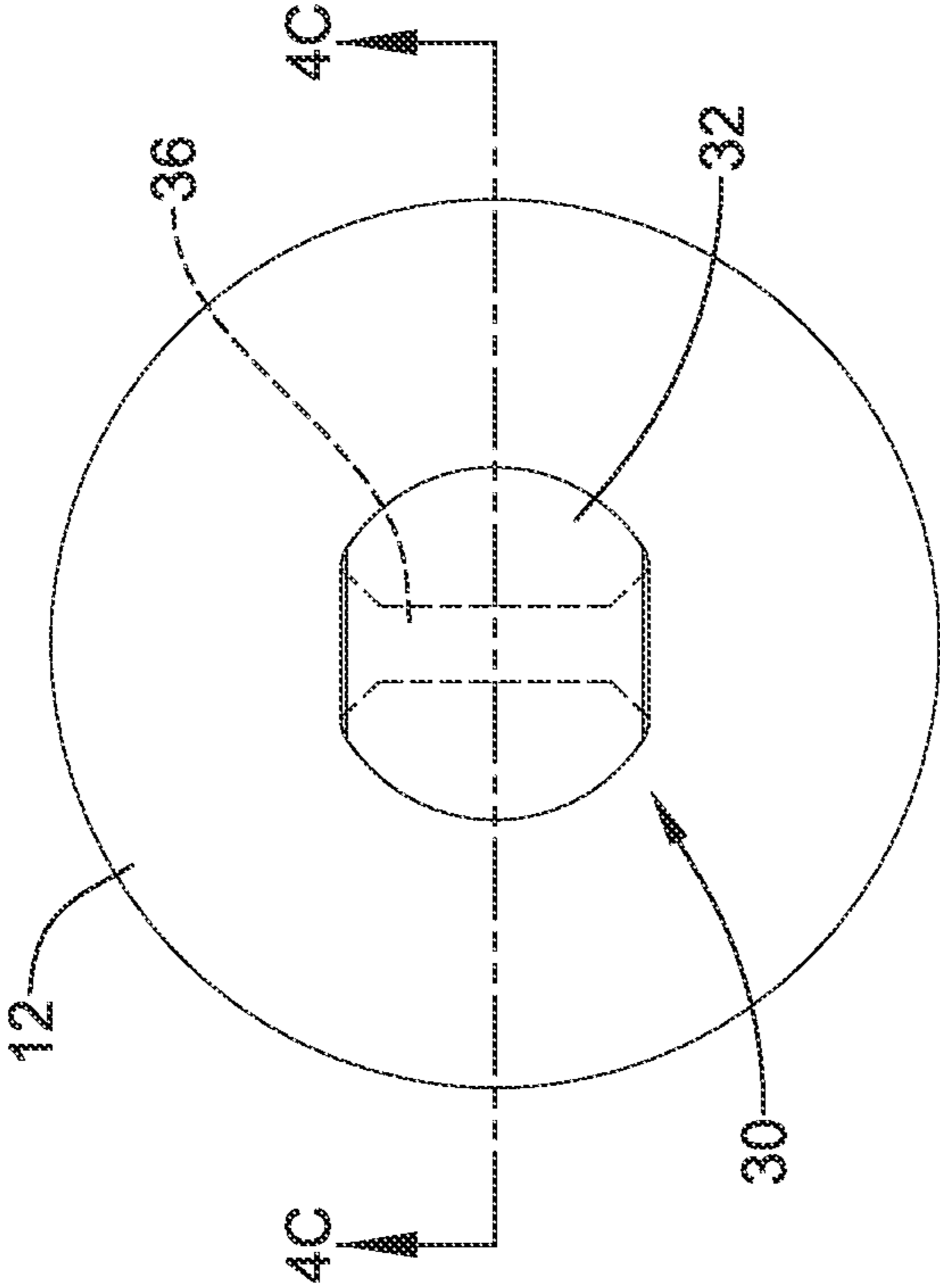


FIG. 4B

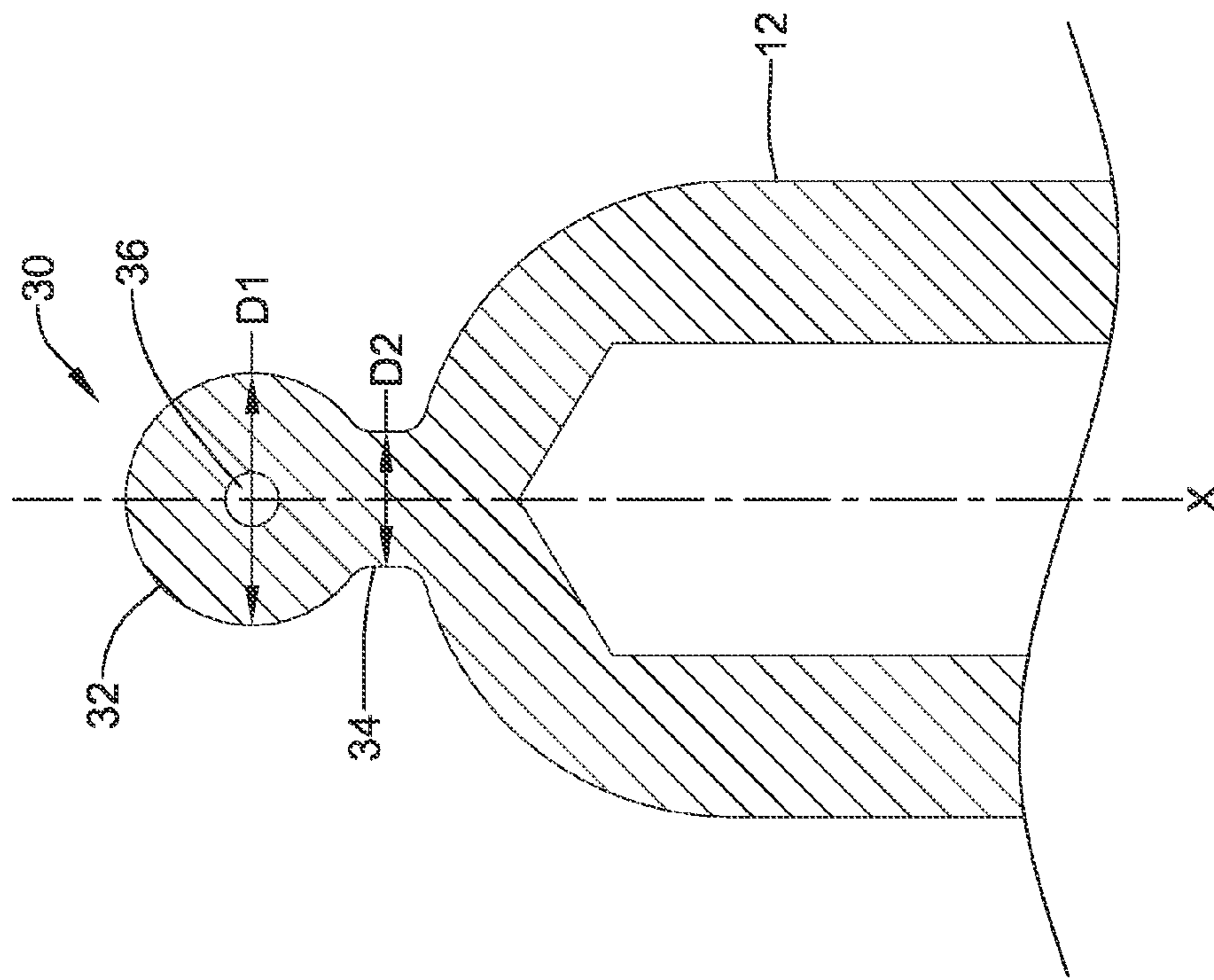


FIG. 4C

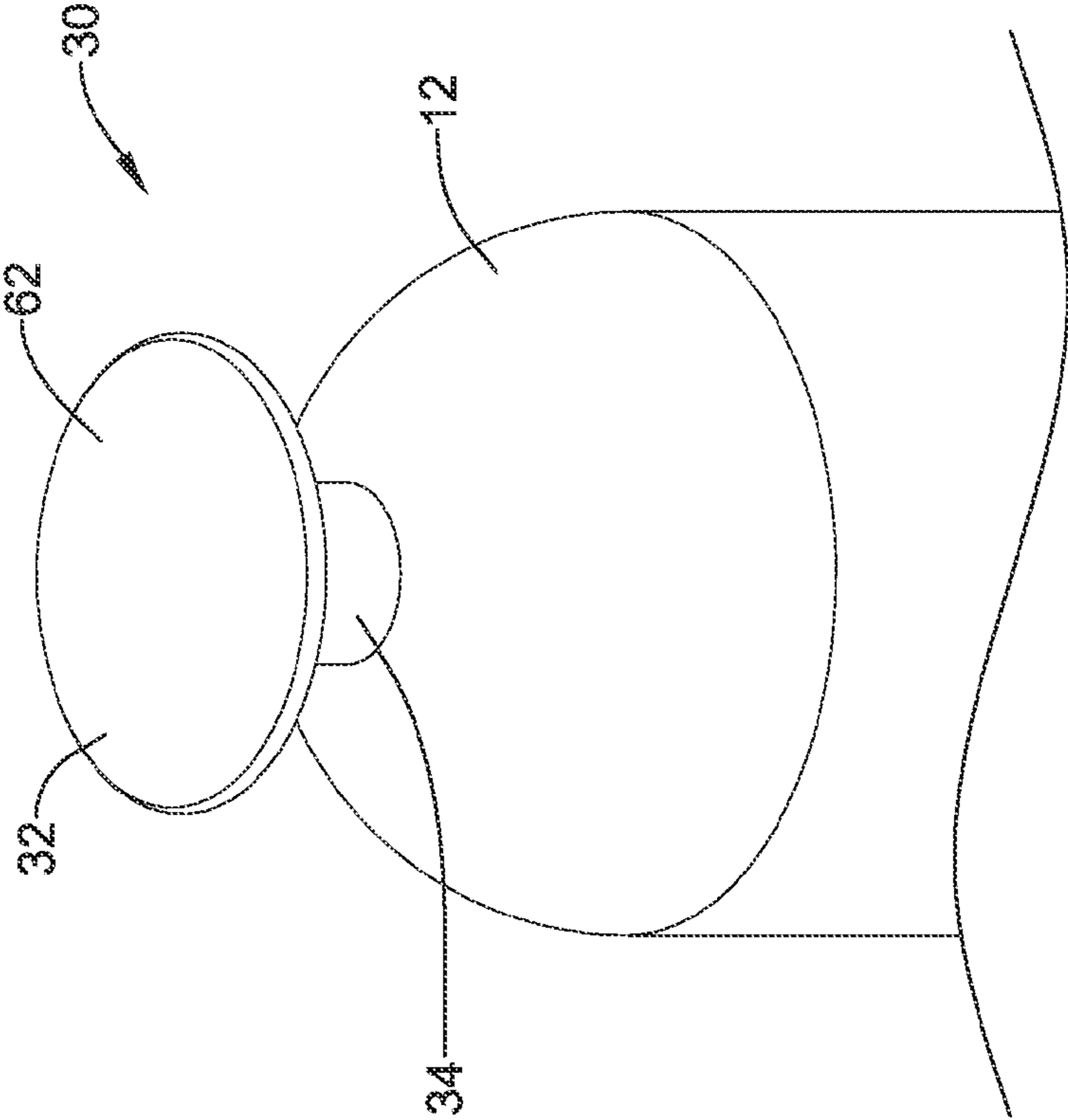


FIG. 5A

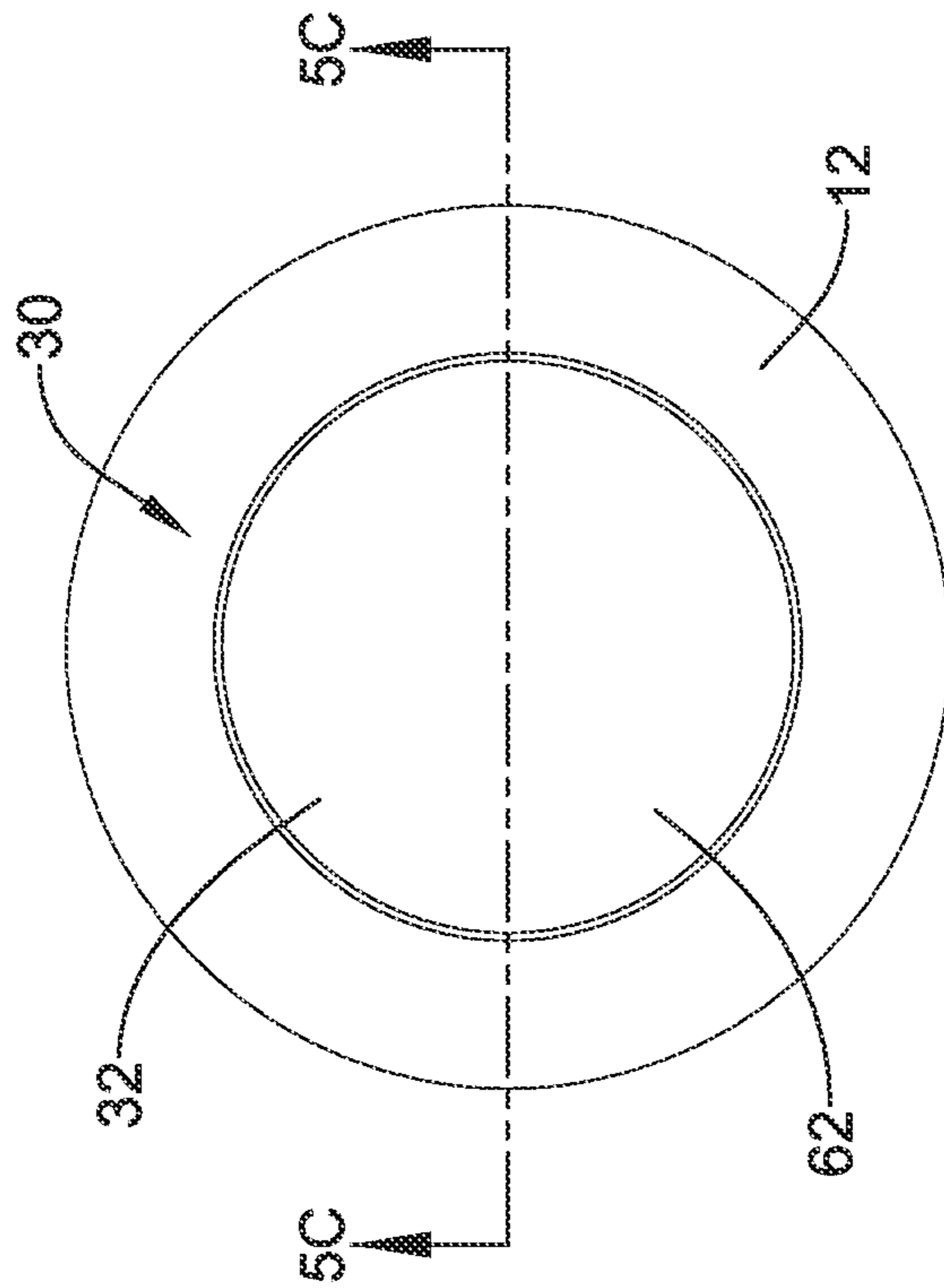


FIG. 5B

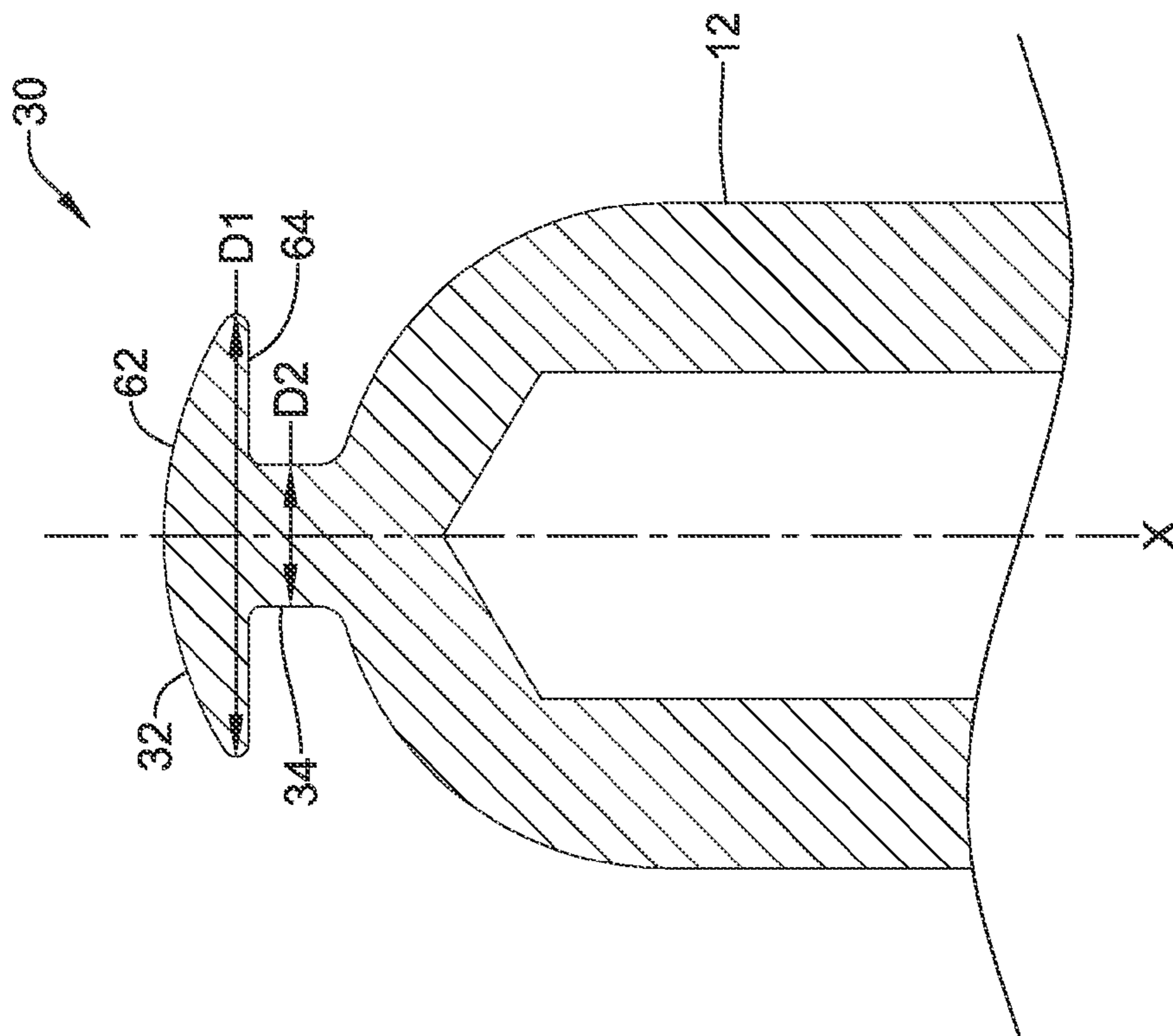


FIG. 5C

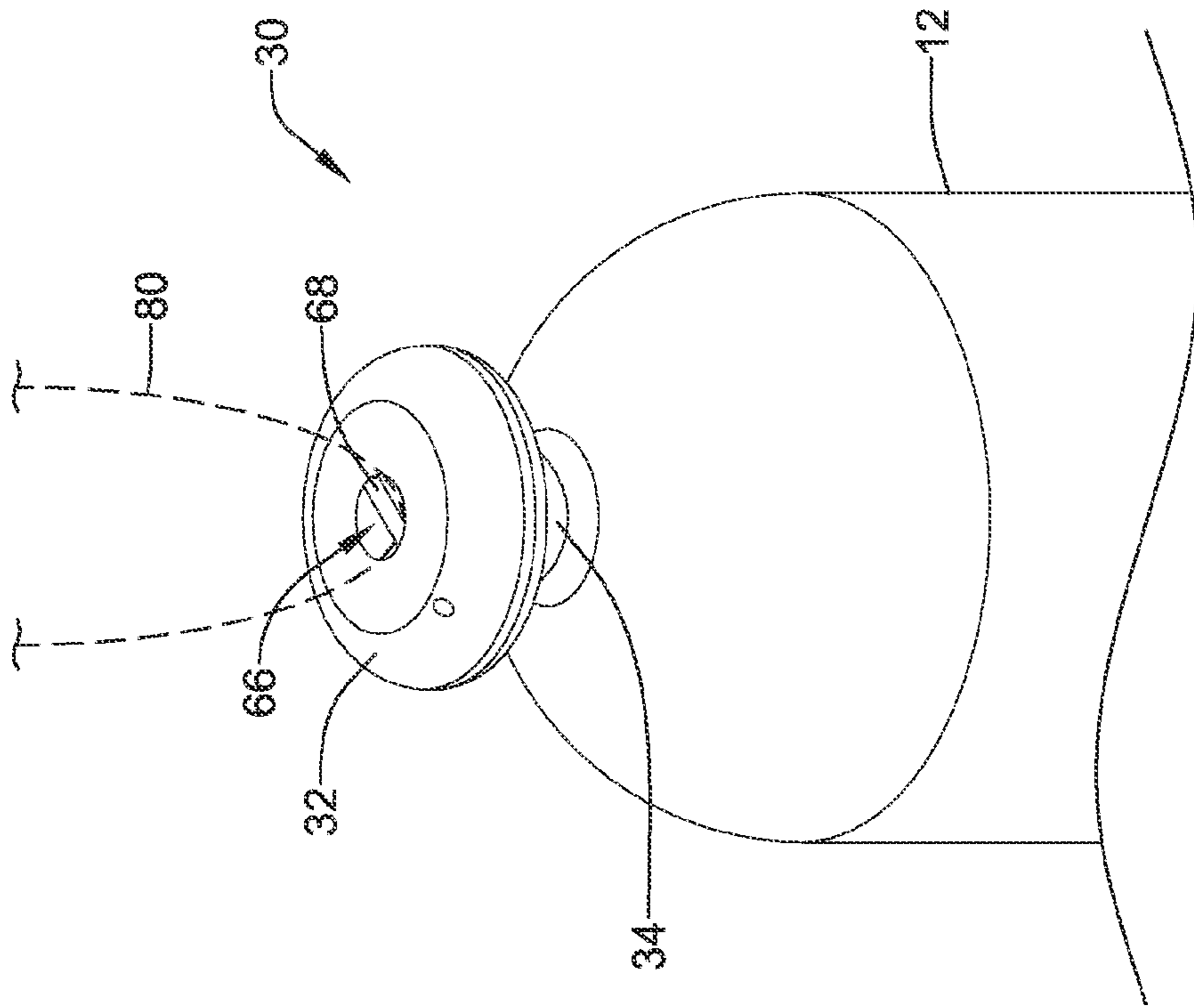


FIG. 6A

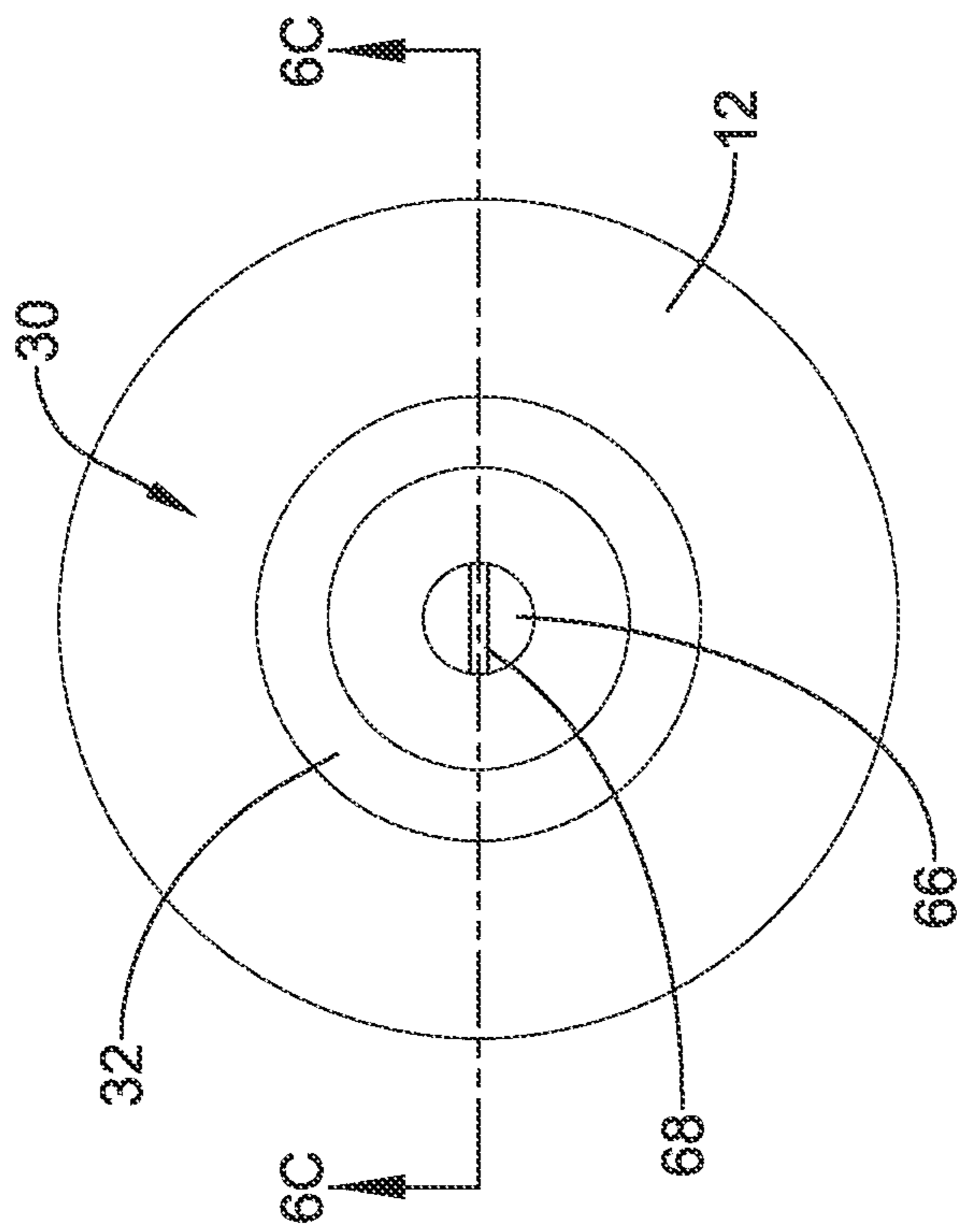


FIG. 6B

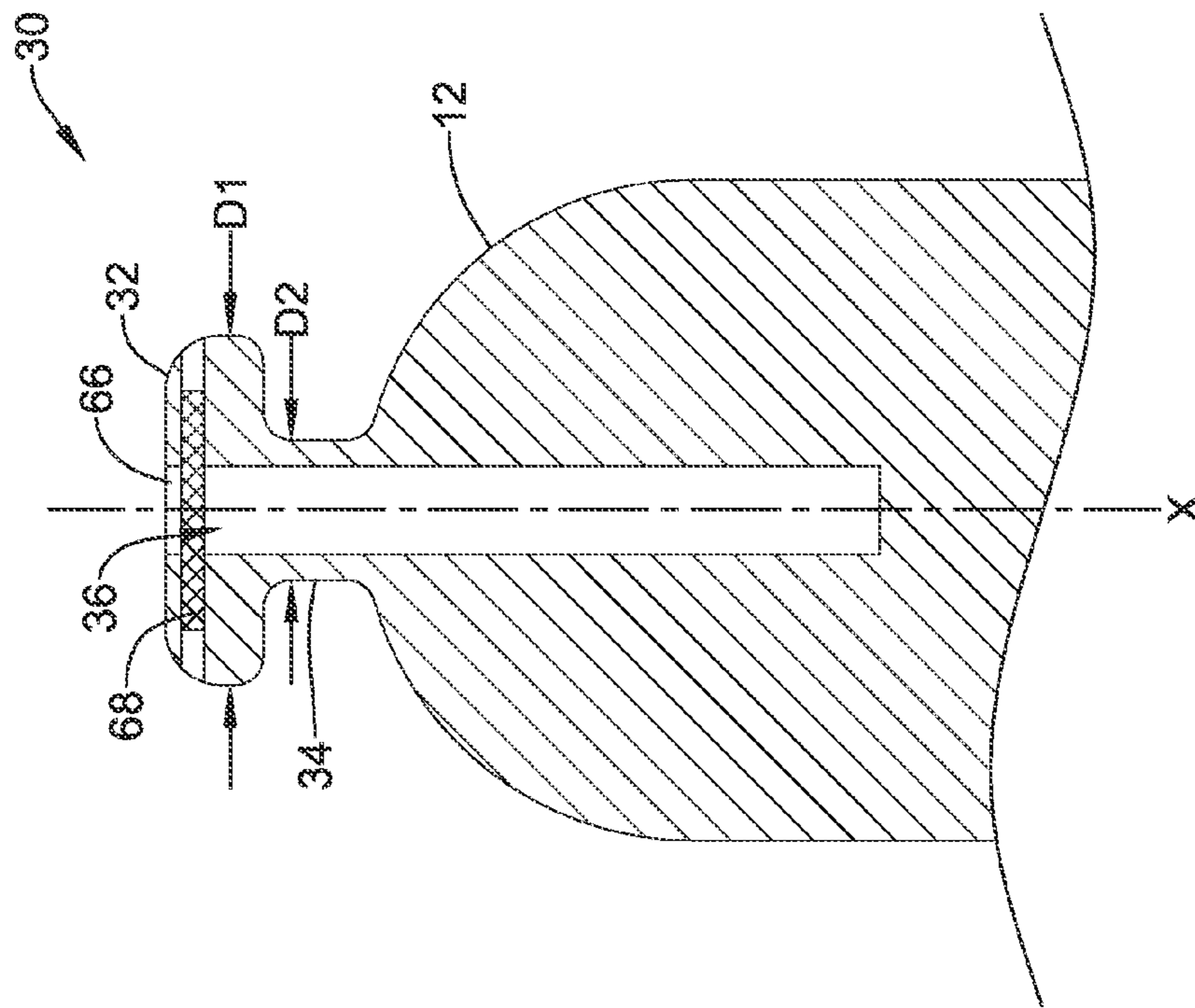


FIG. 6C

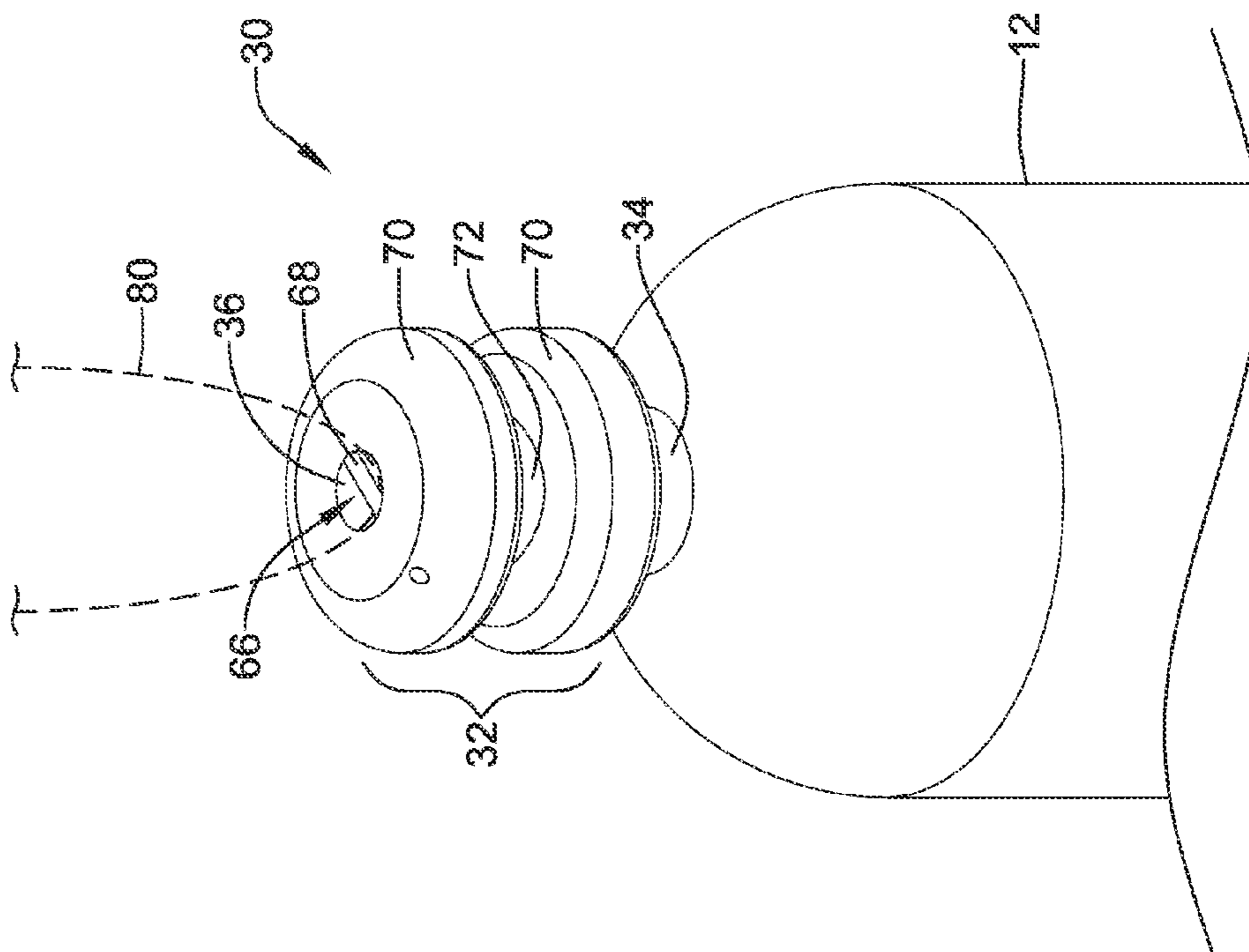


FIG. 7A

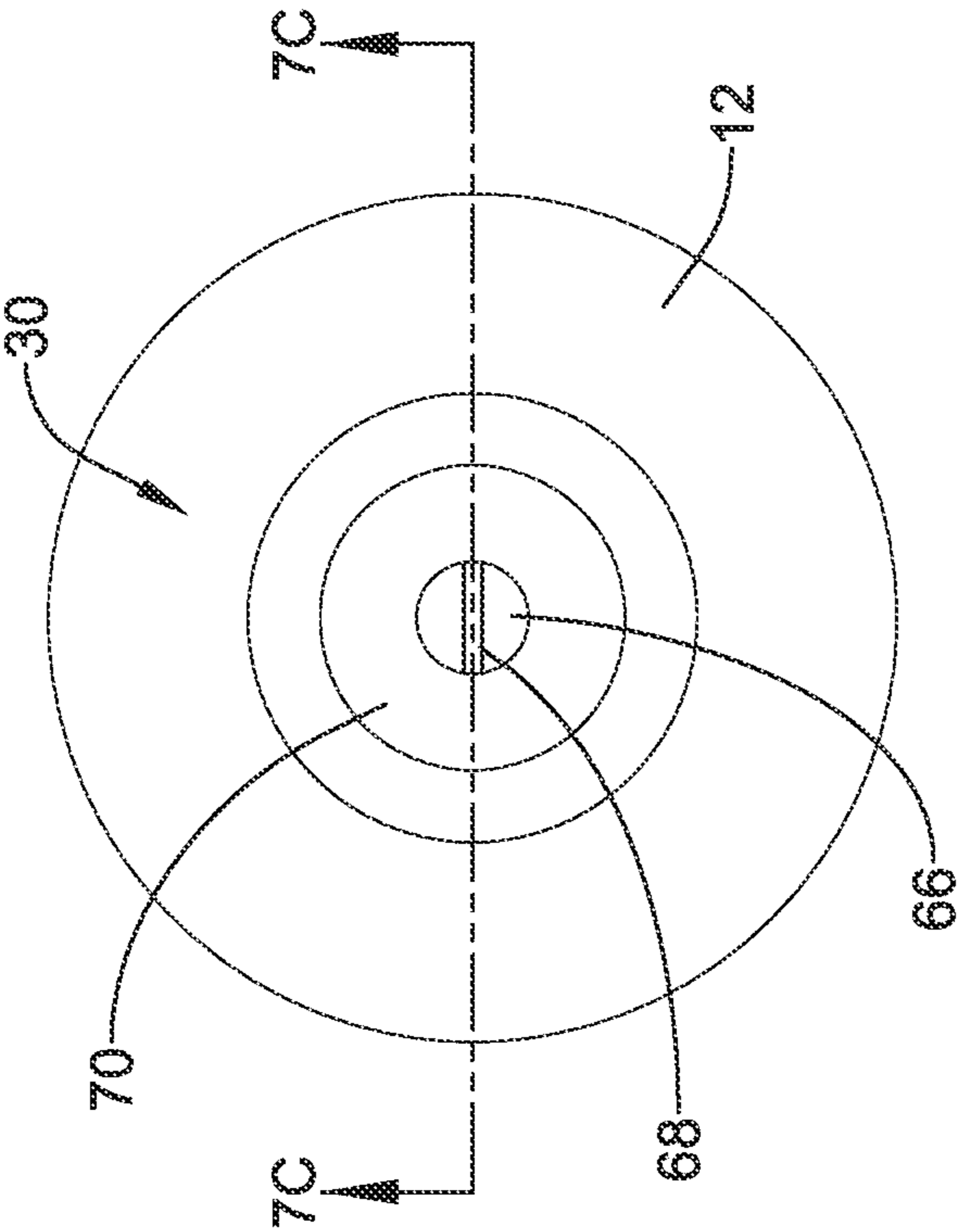


FIG. 7B

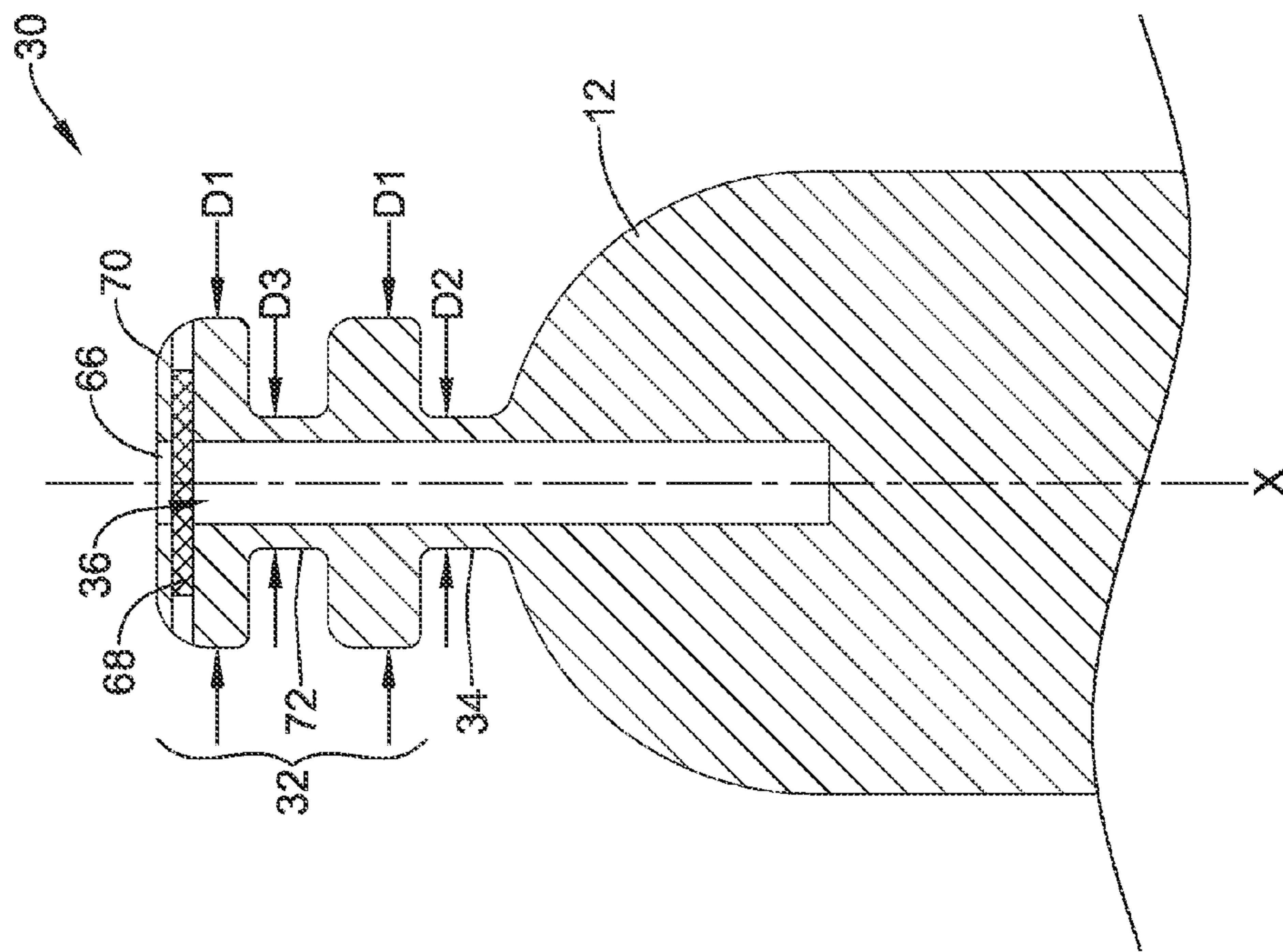


FIG. 7C

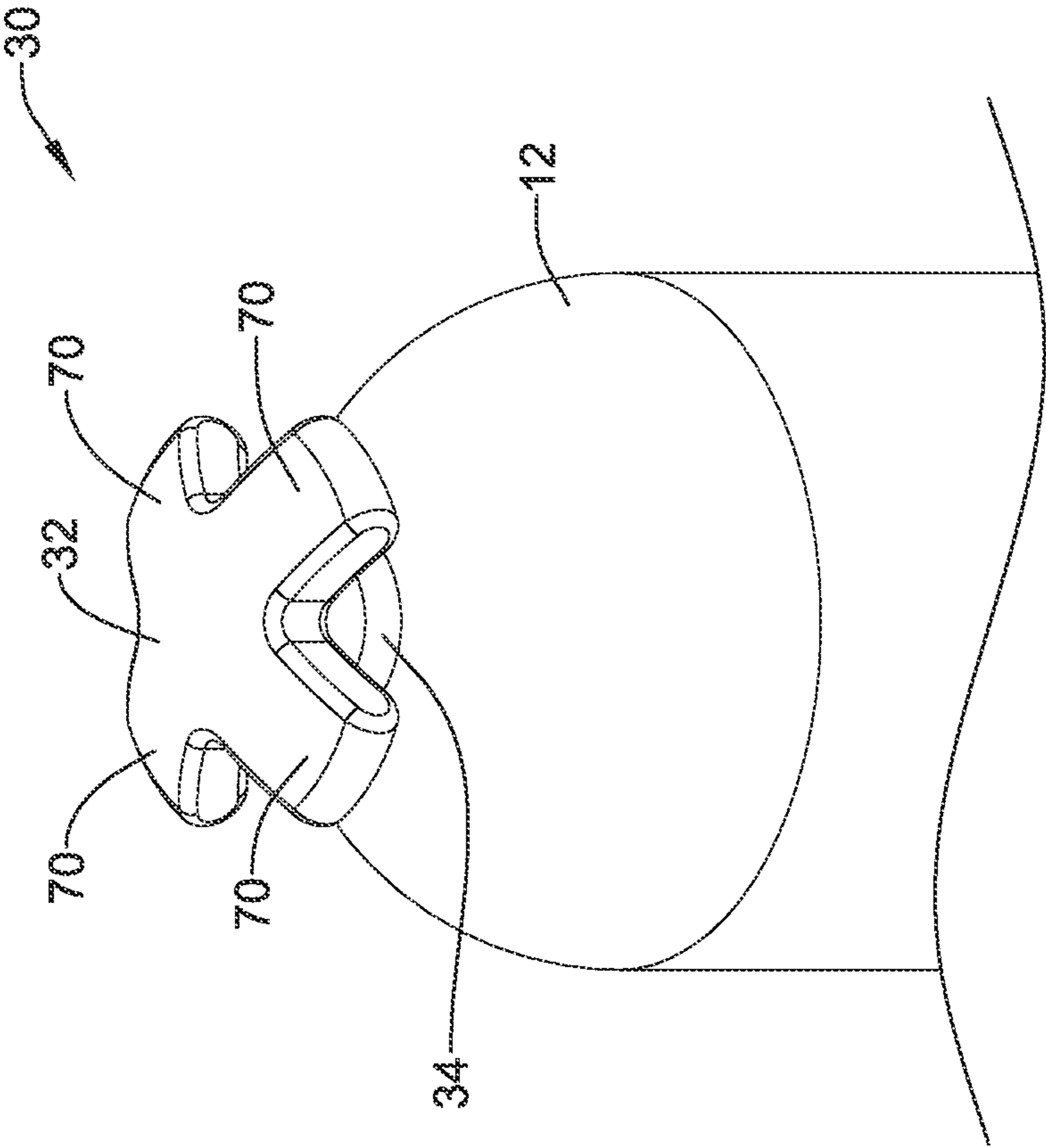


FIG. 8A

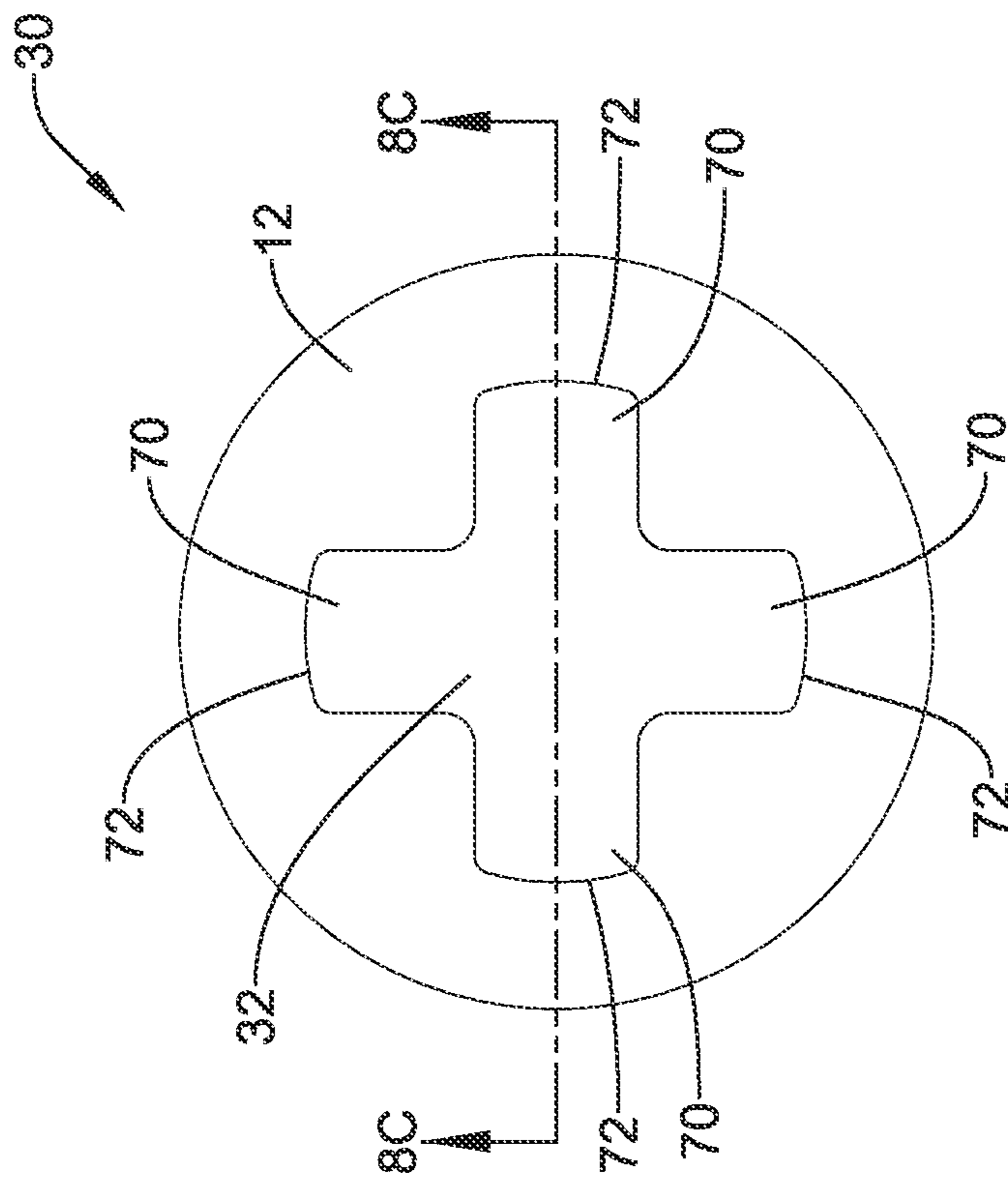


FIG. 8B

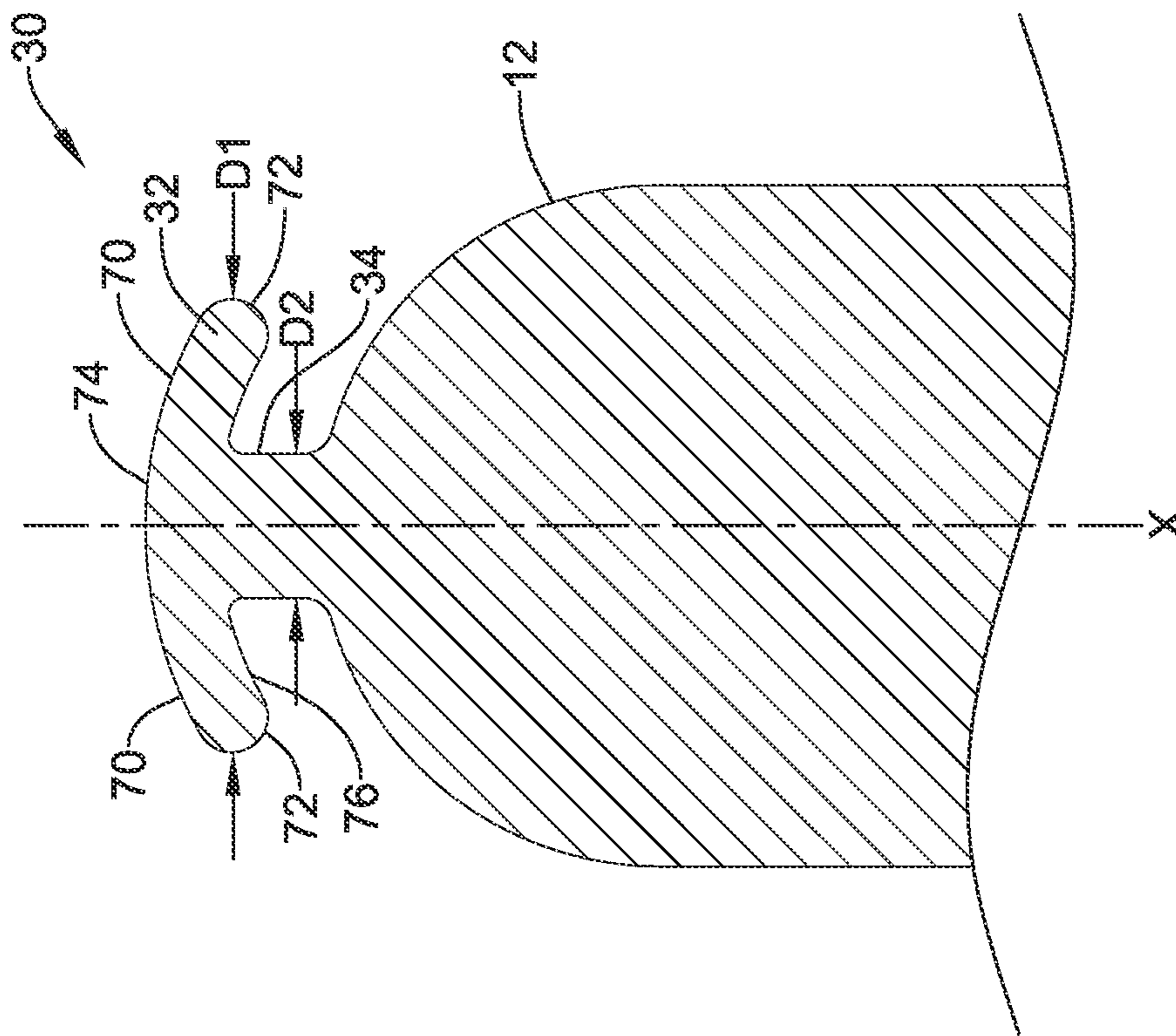


FIG. 8C

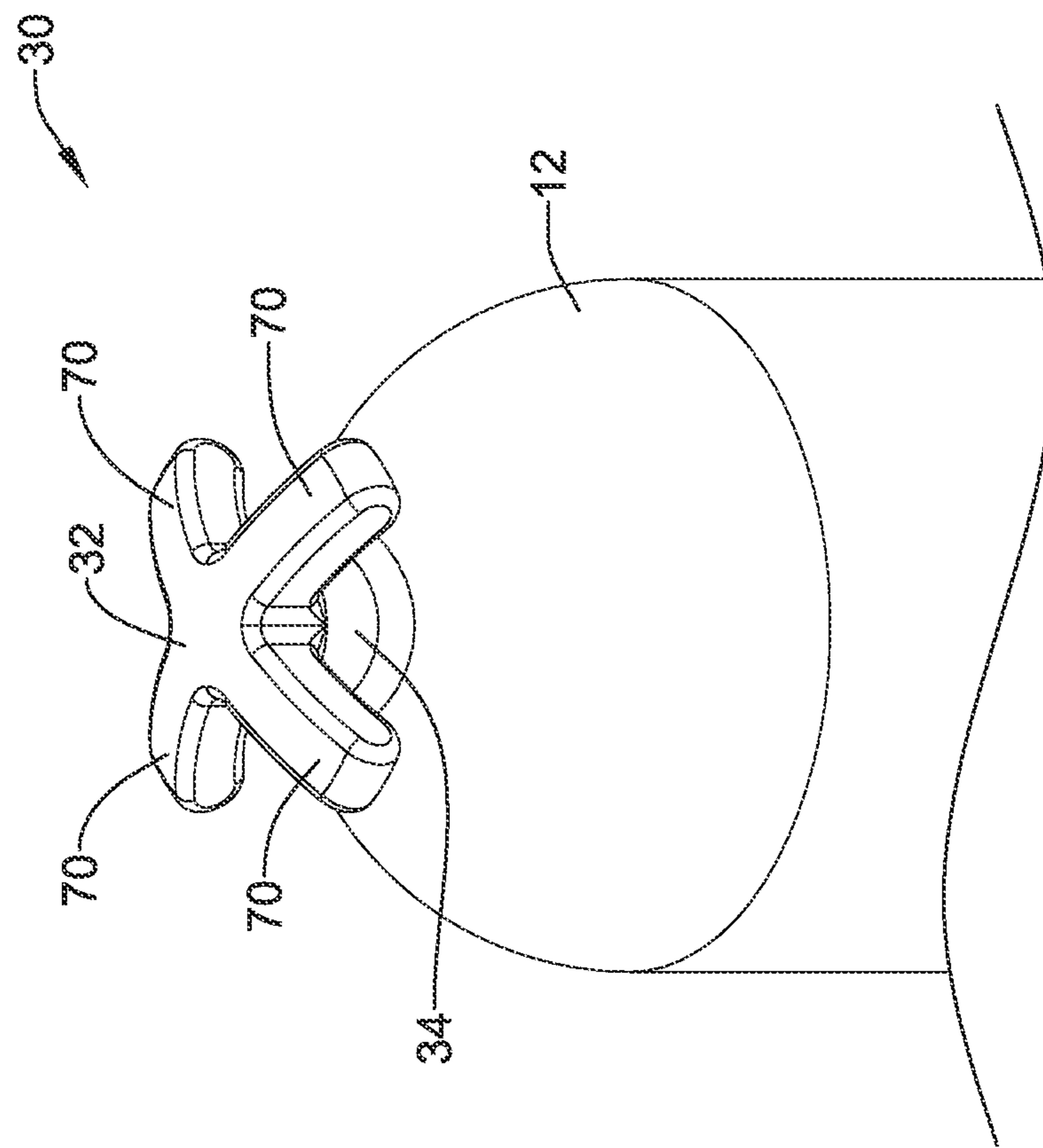


FIG. 9A

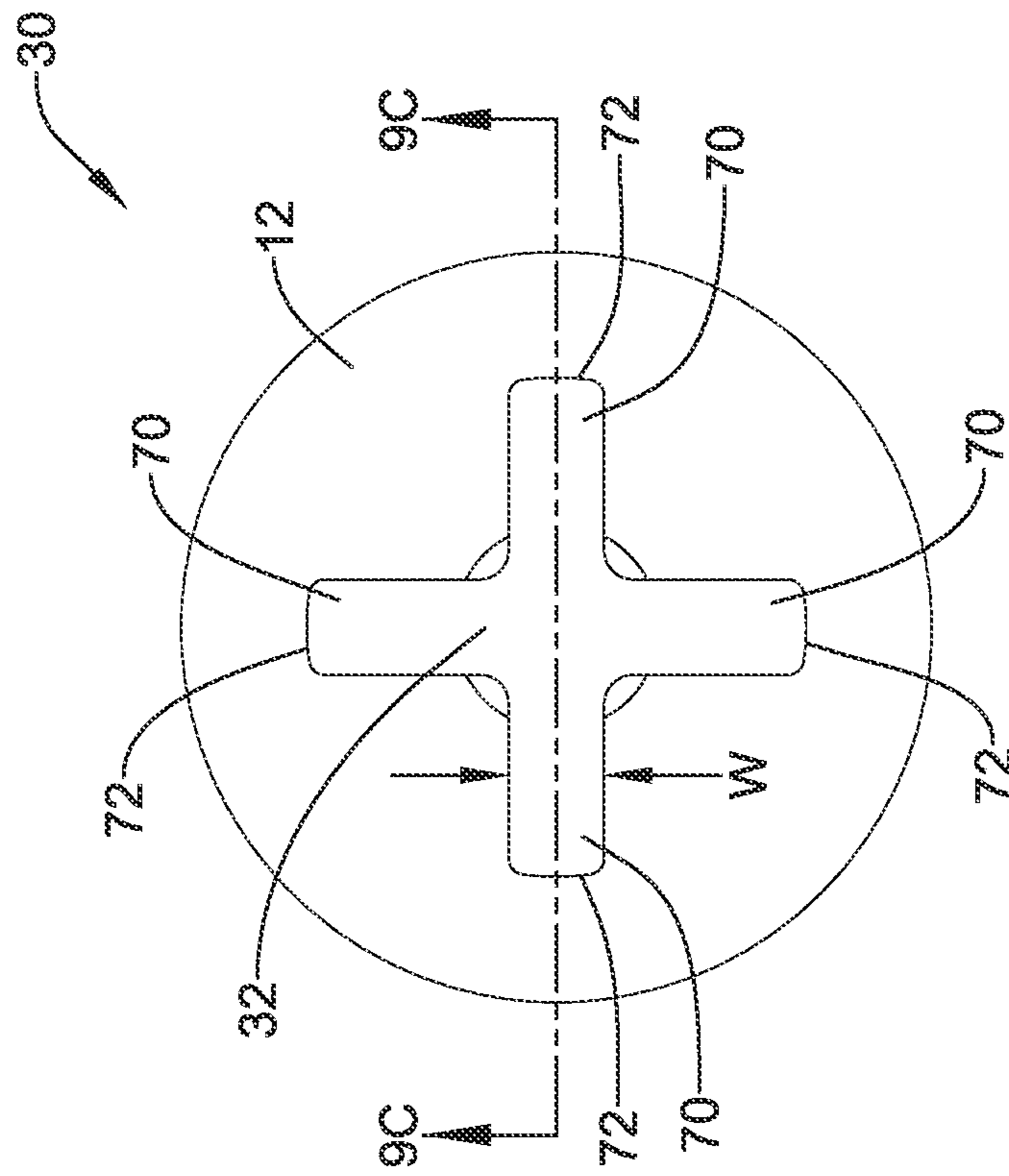


FIG. 9B

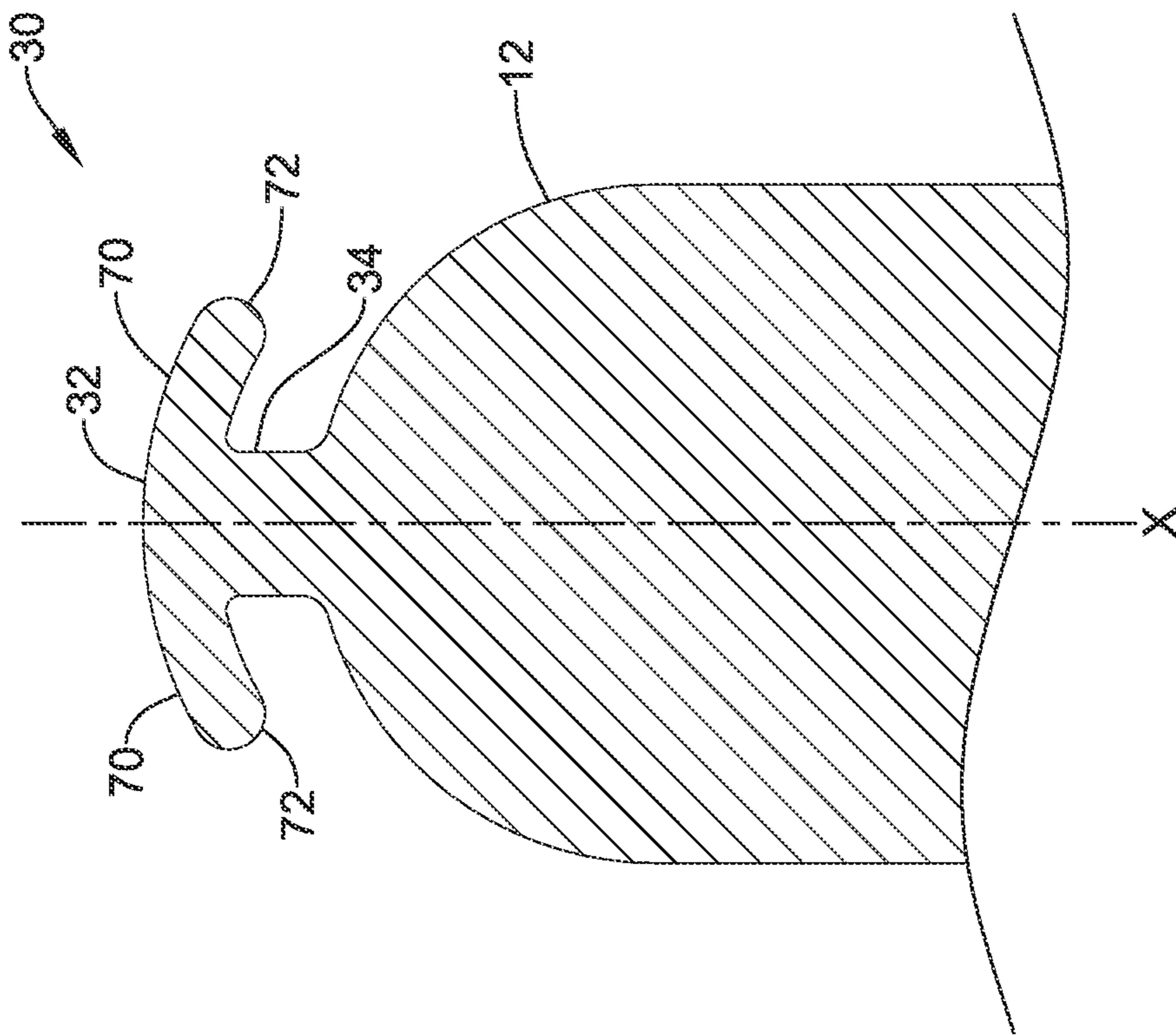


FIG. 9C

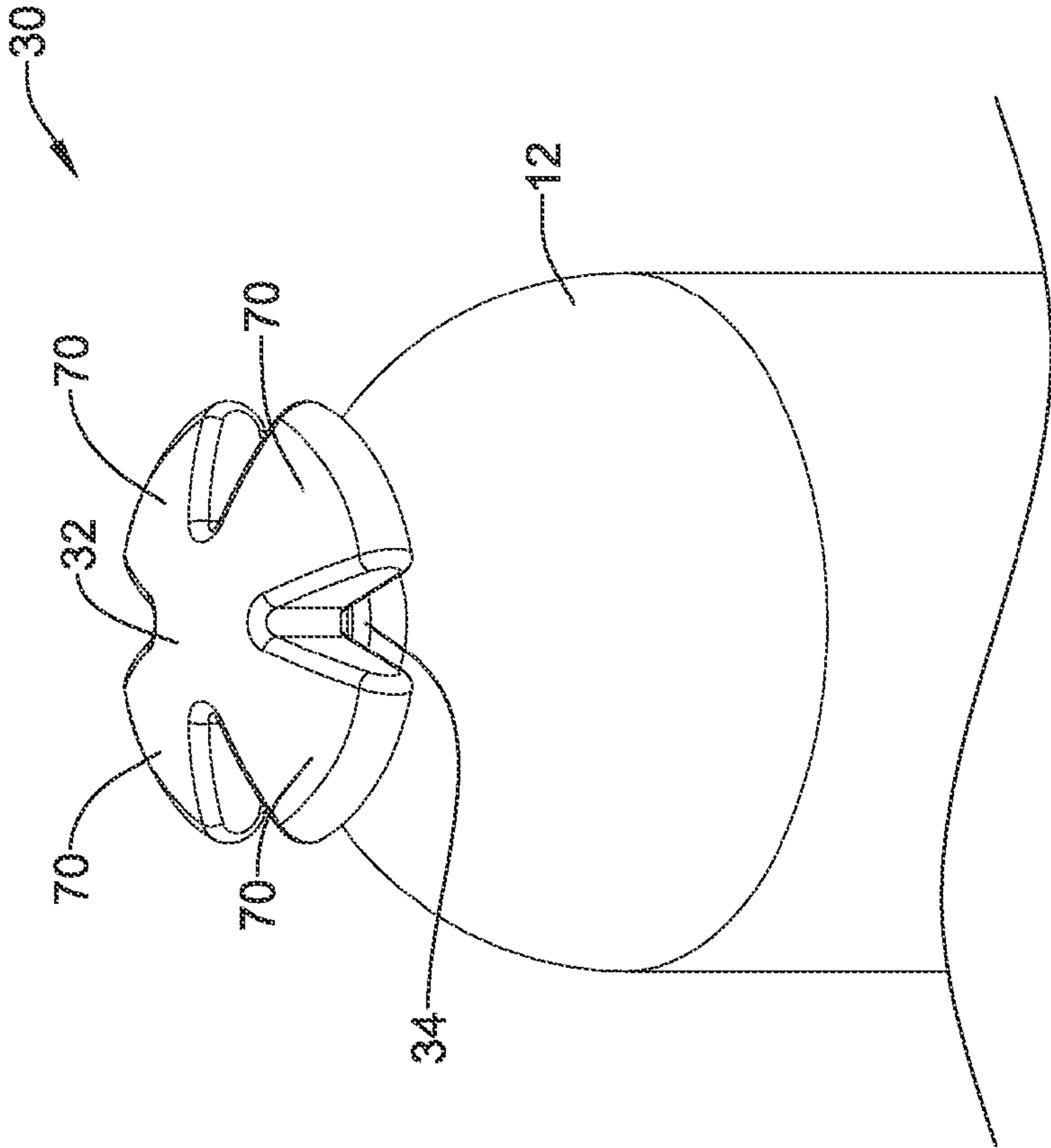


FIG. 10A

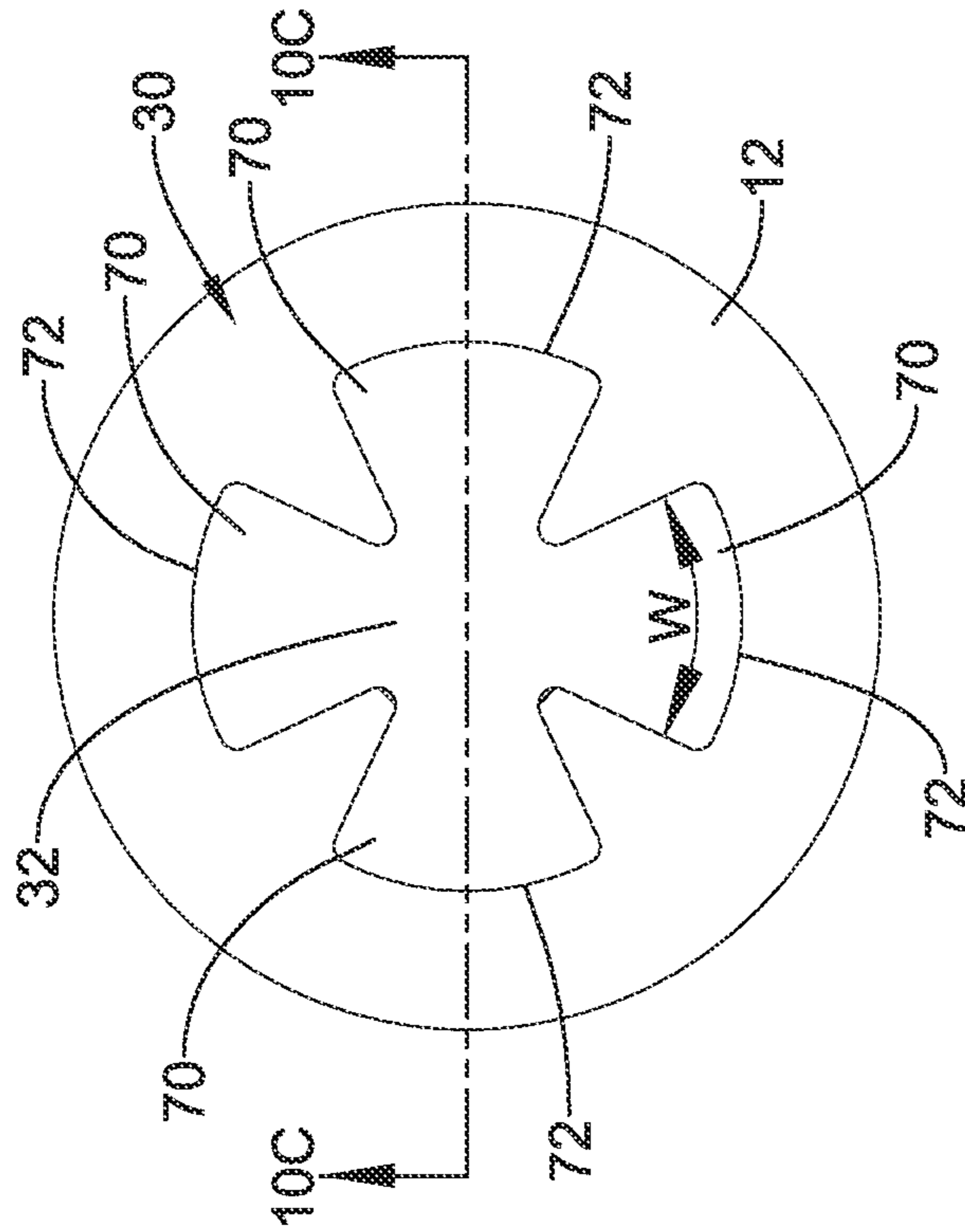


FIG. 10B

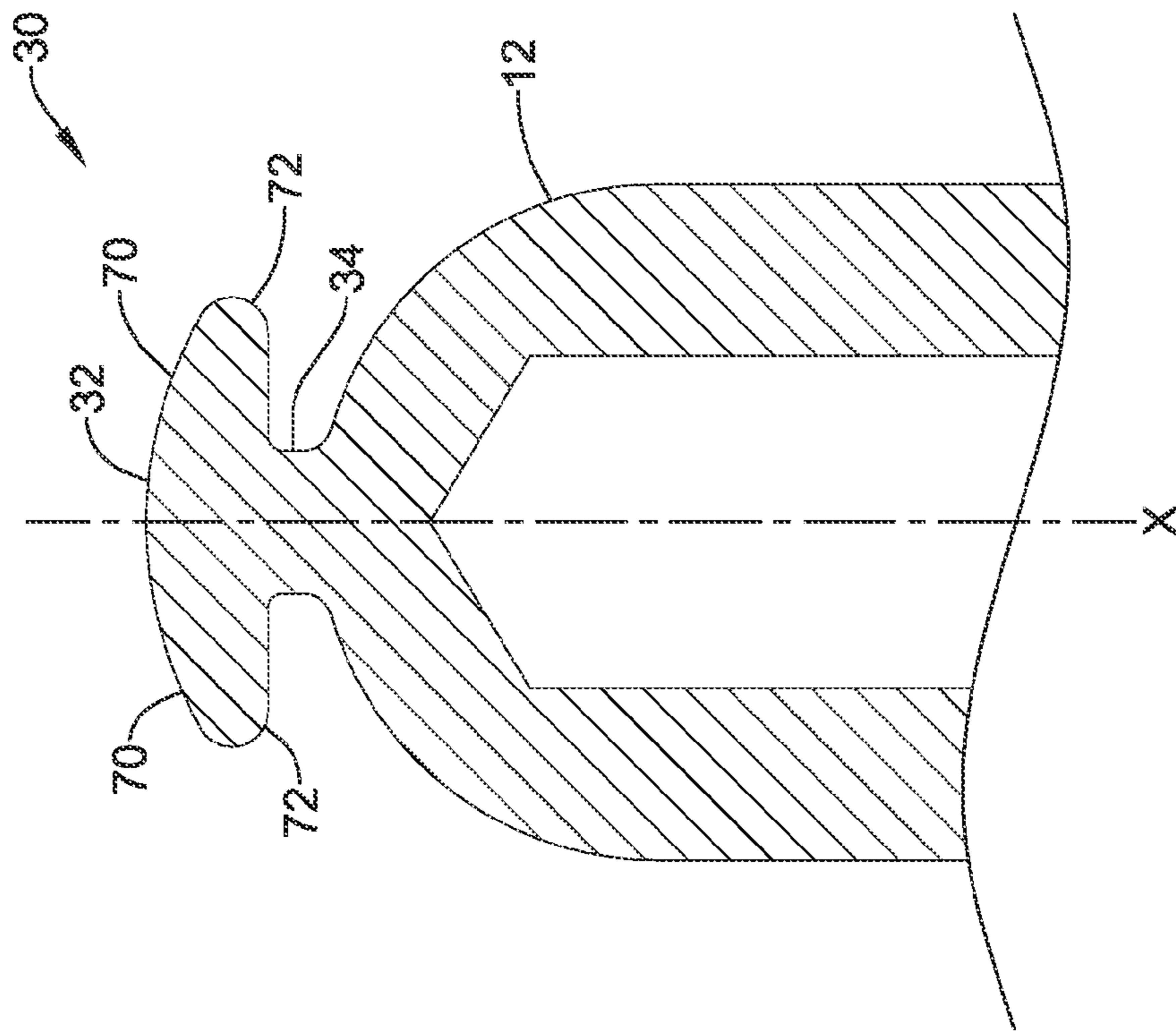


FIG. 10C

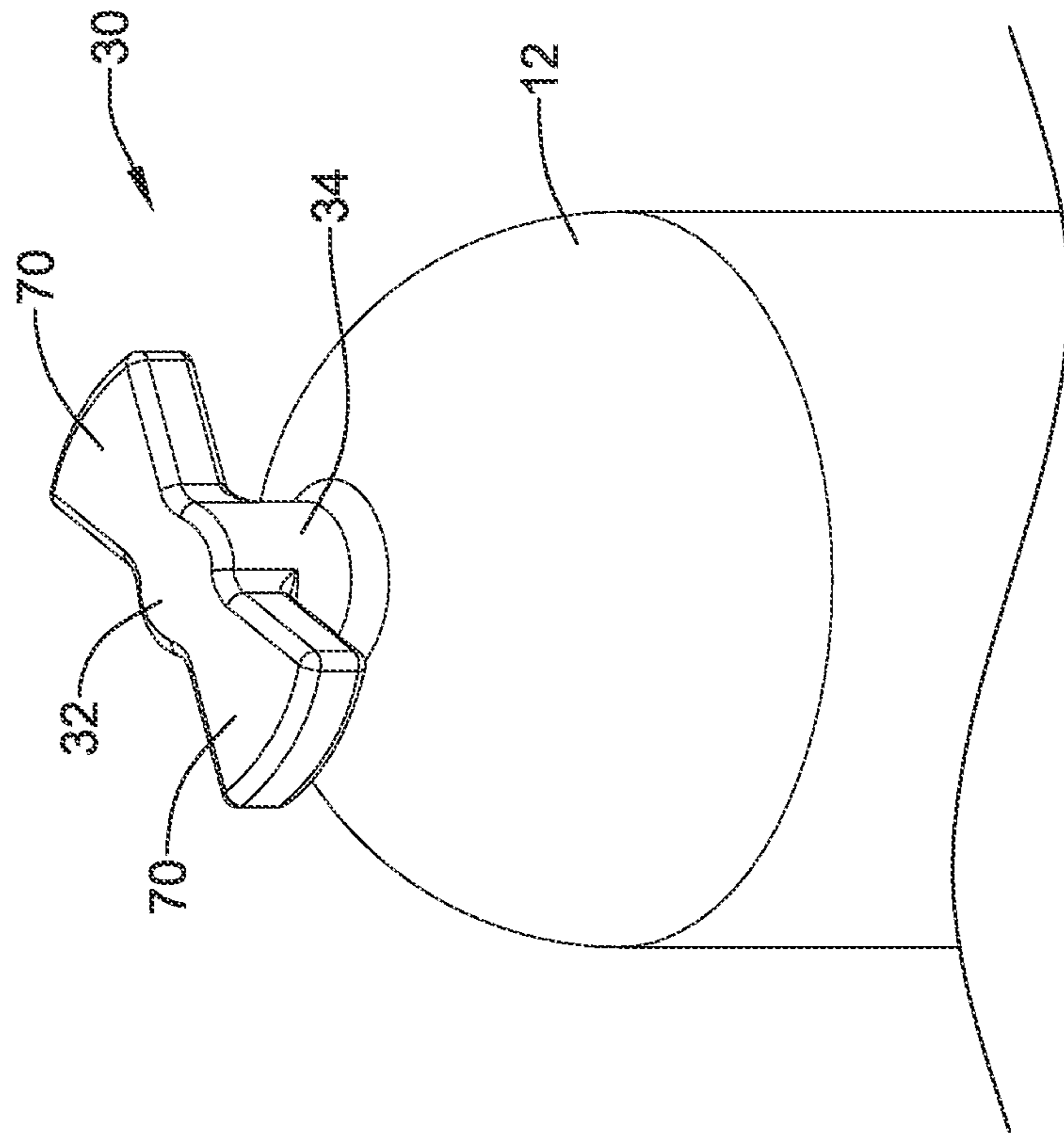


FIG. 11A

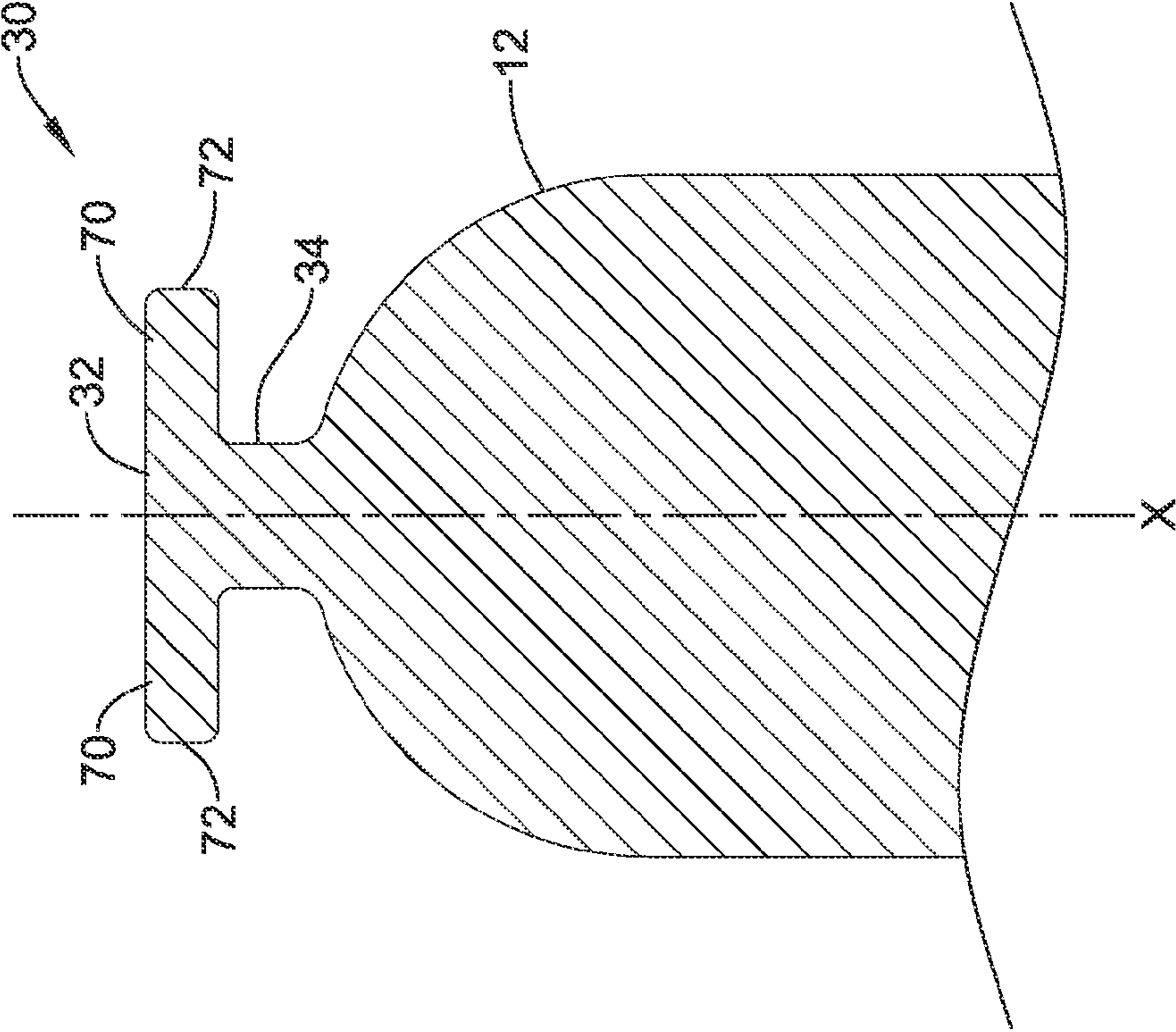


FIG. 11C

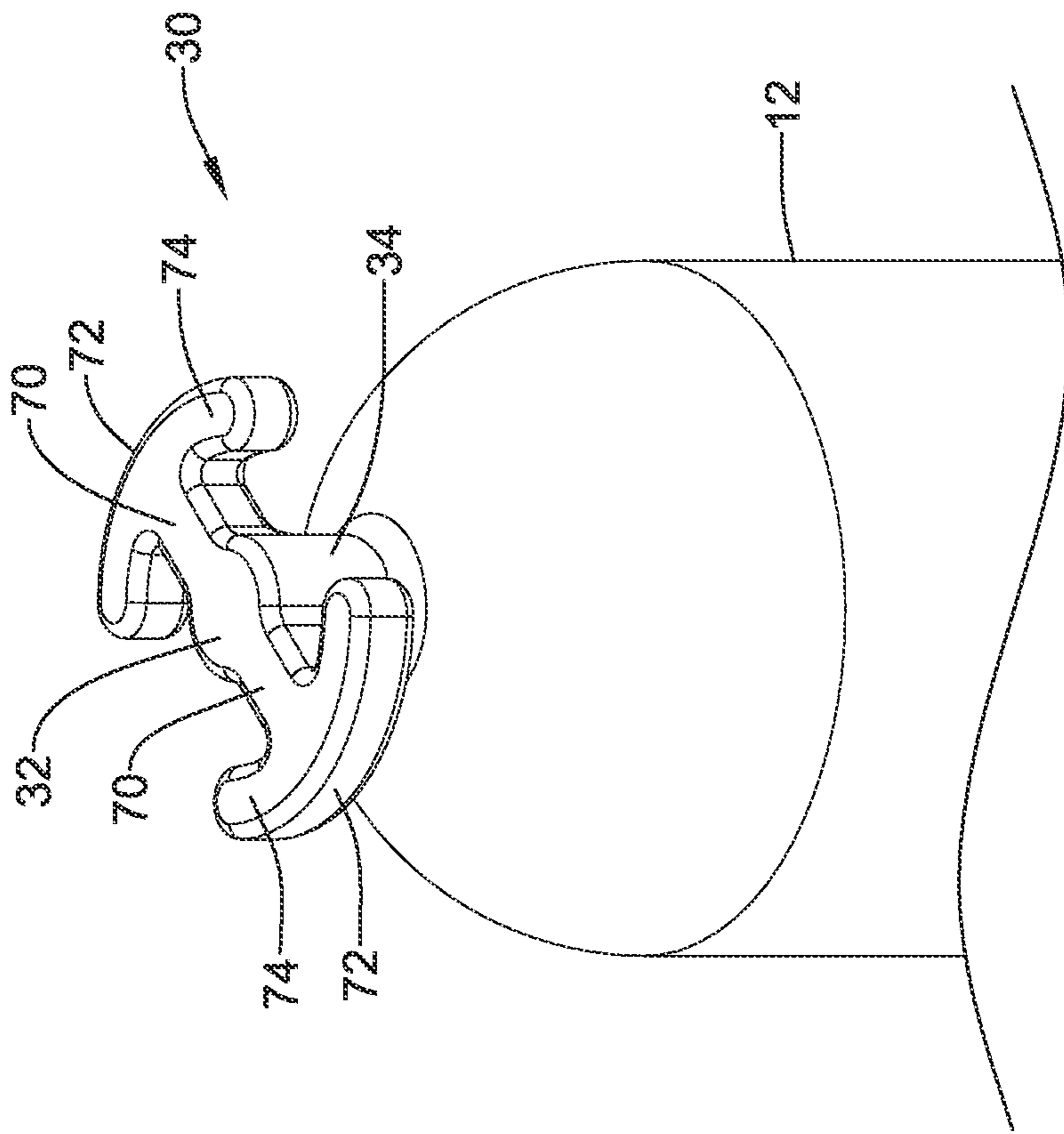


FIG. 12A

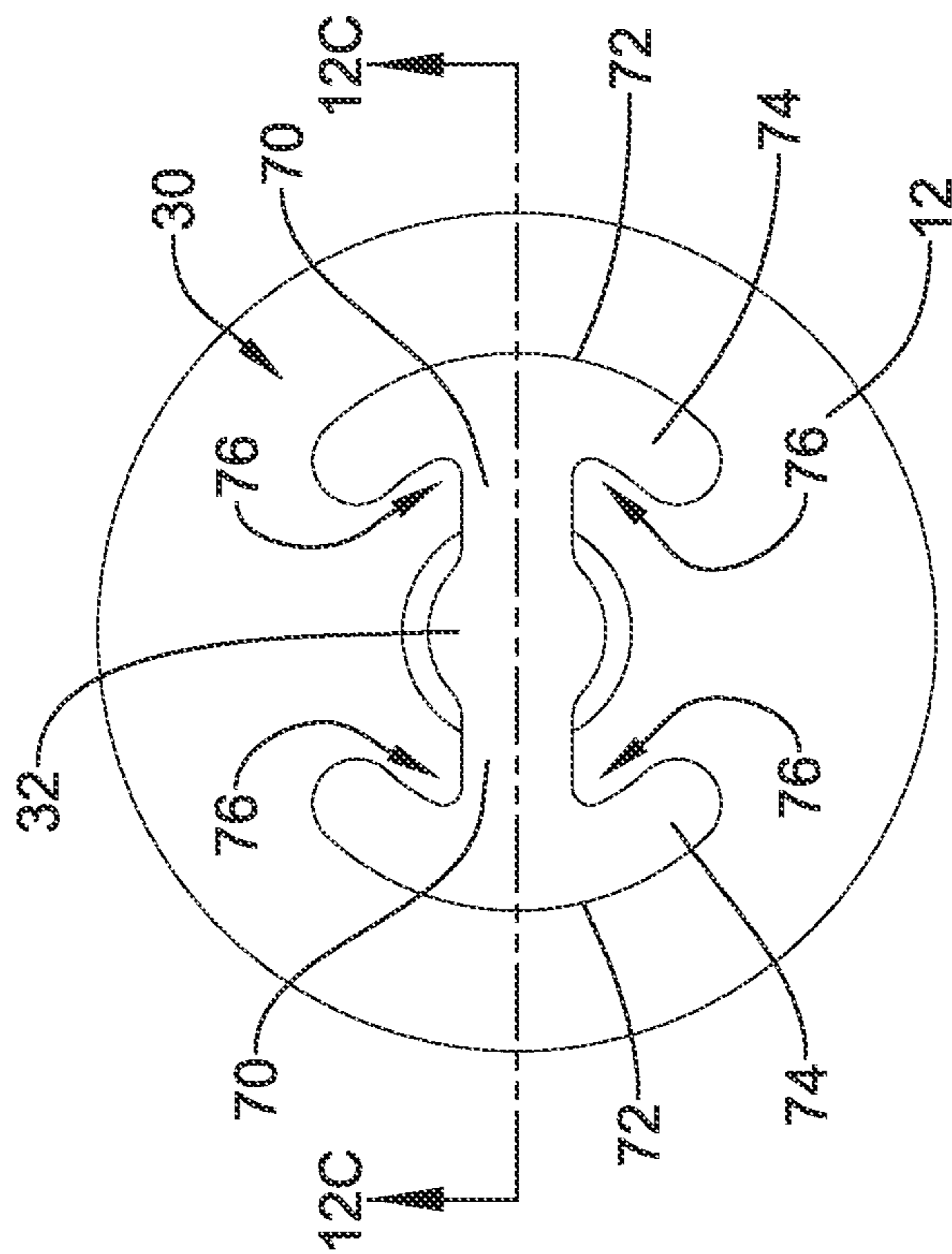


FIG. 12B

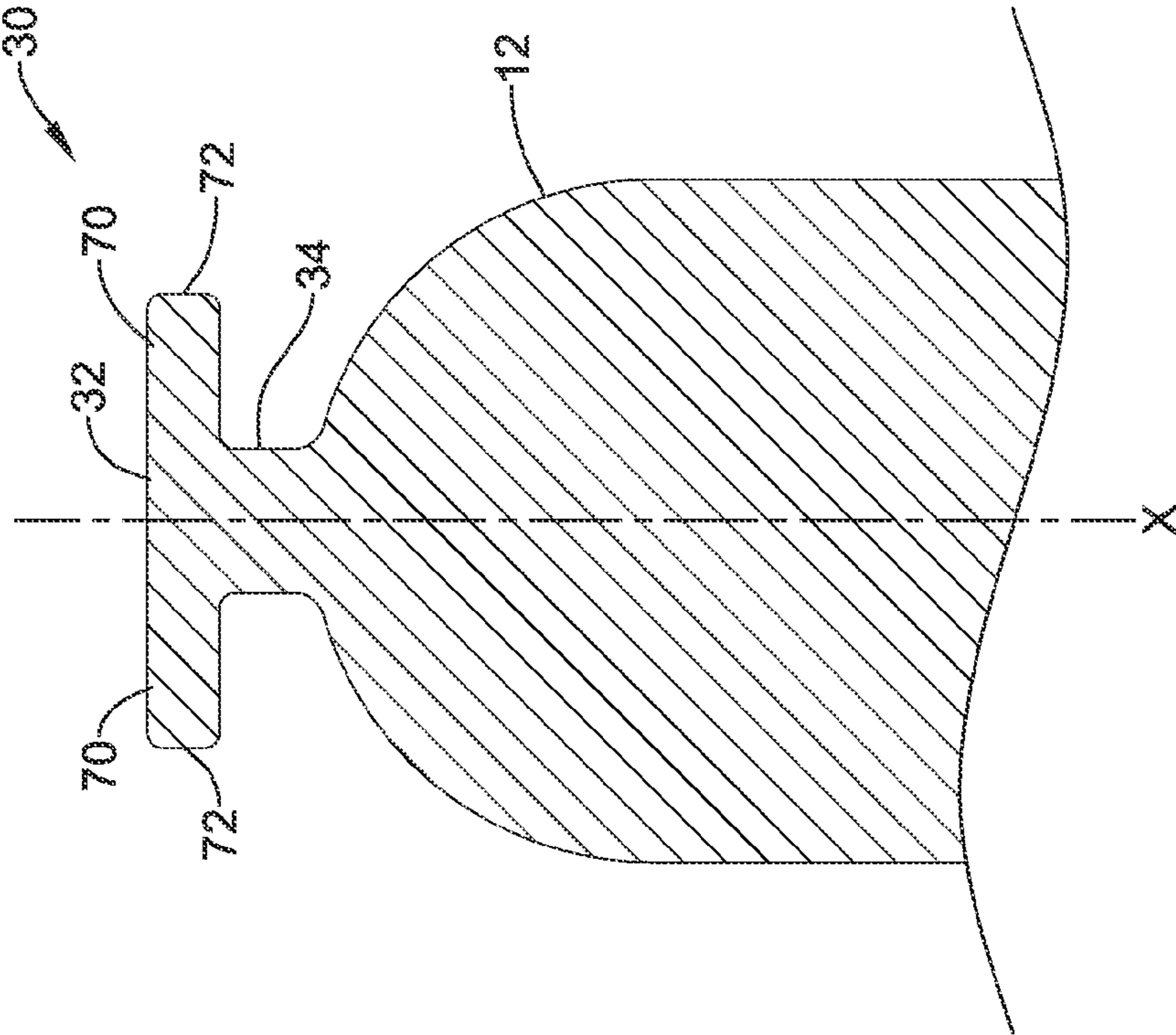


FIG. 12C

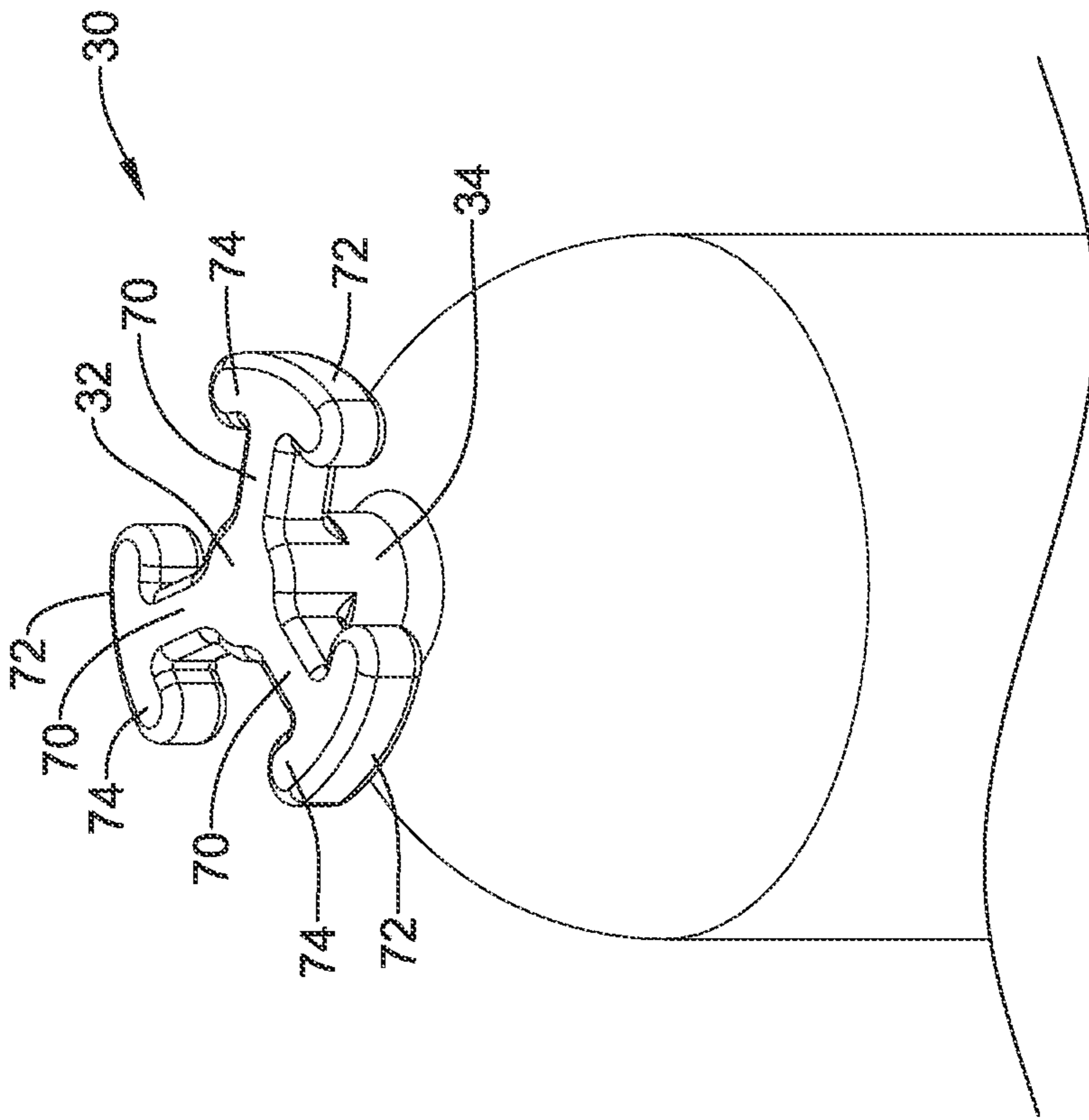


FIG. 13A

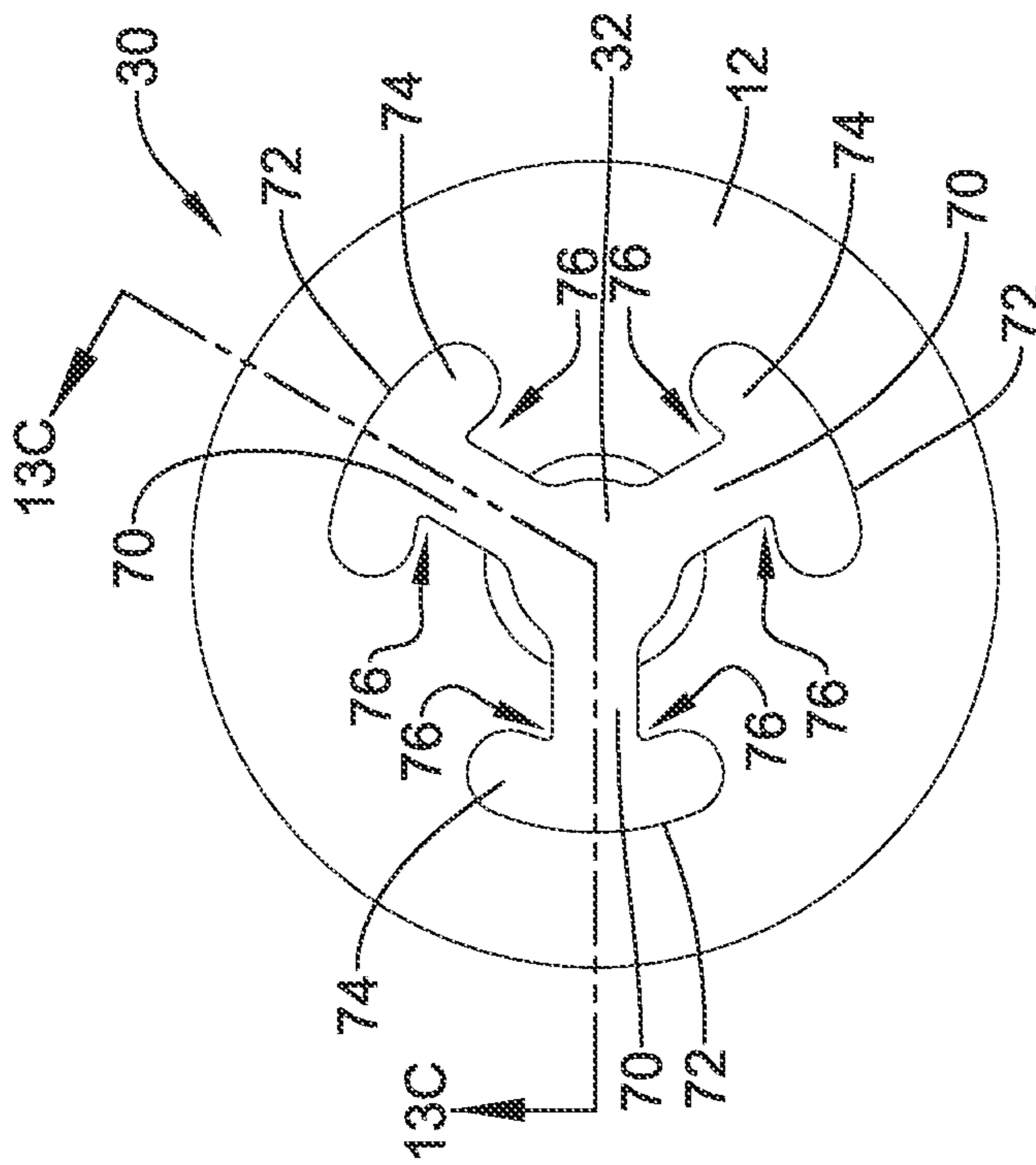


FIG. 13B

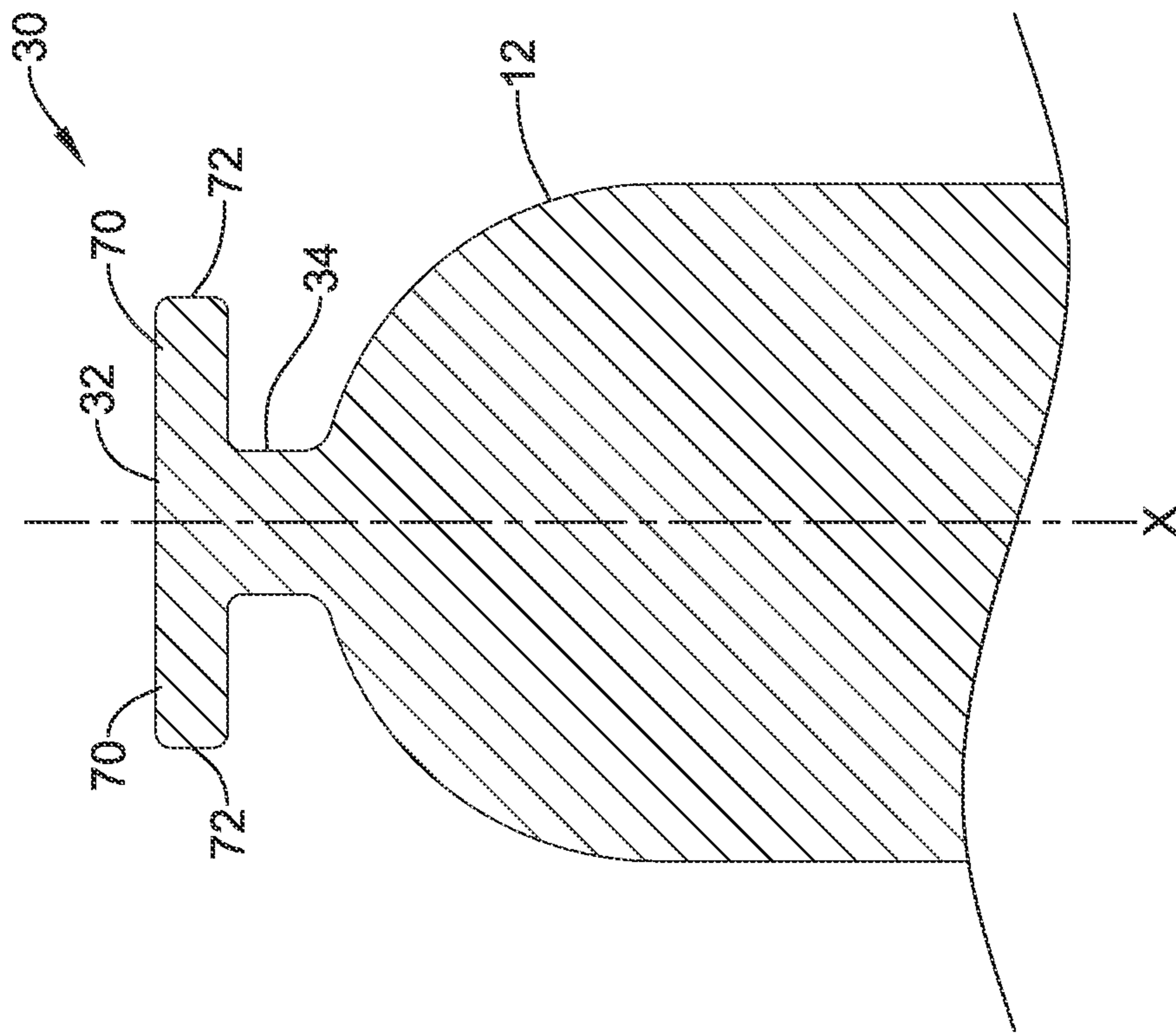


FIG. 13C

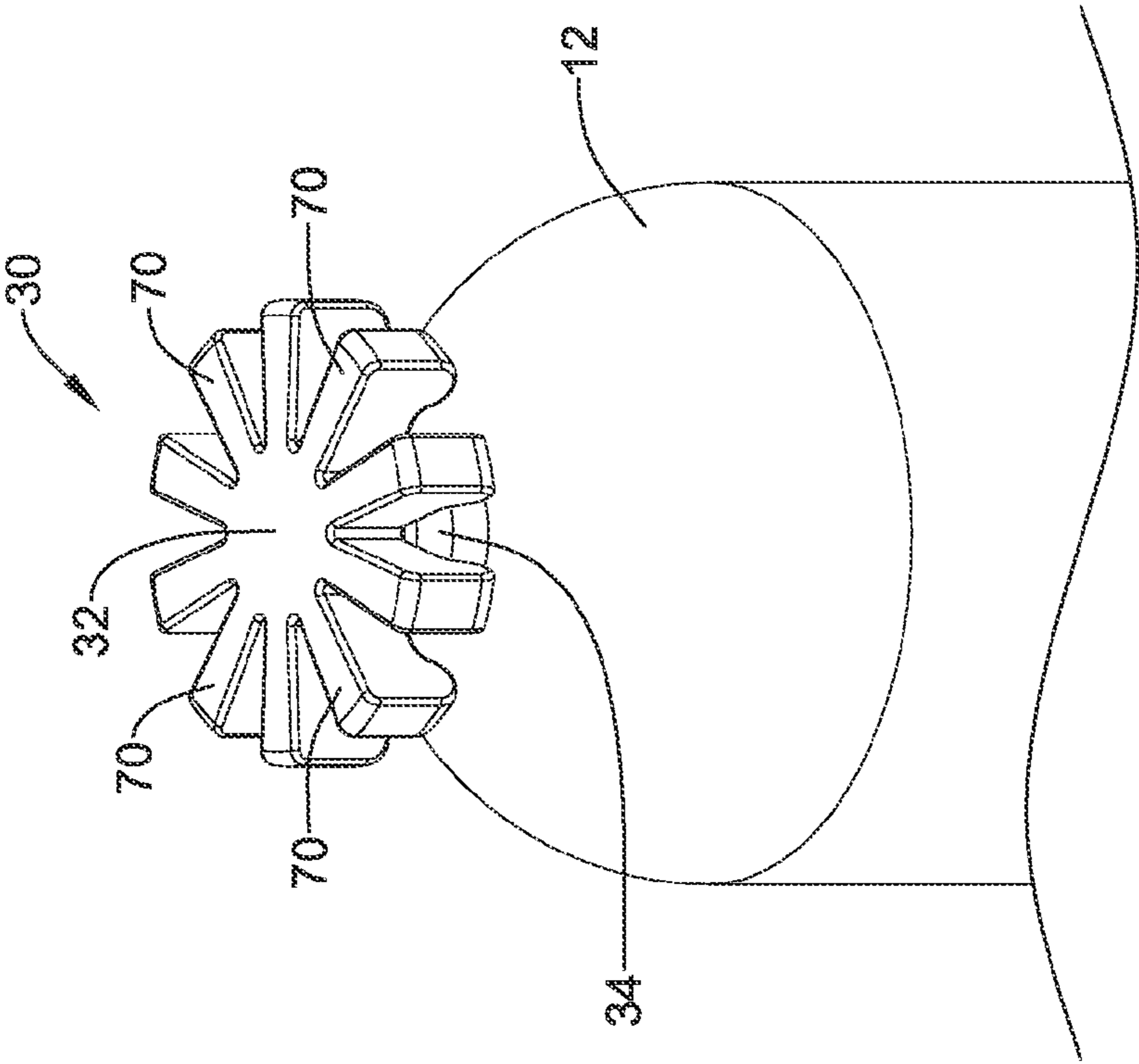


FIG. 14A

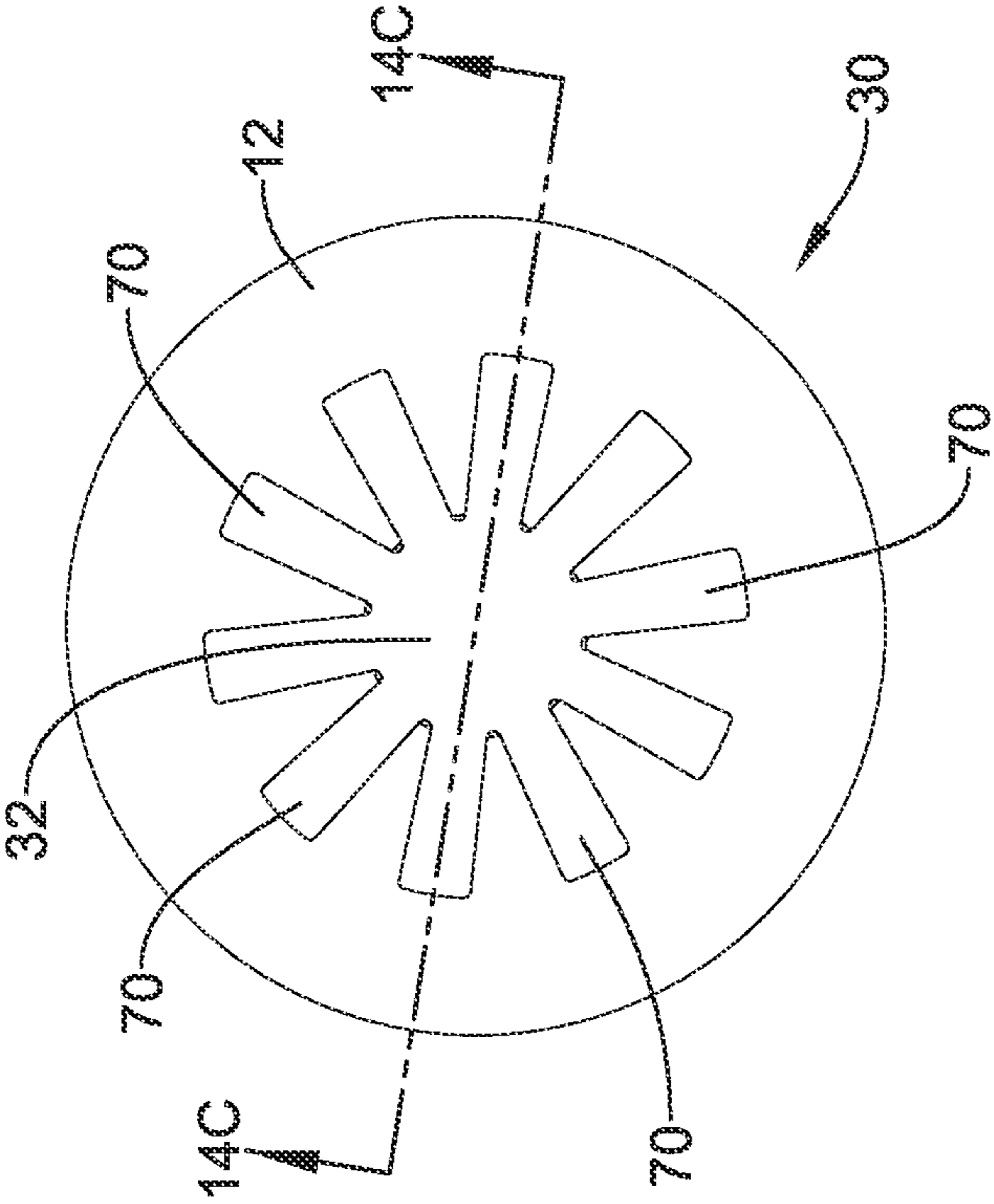


FIG. 14B

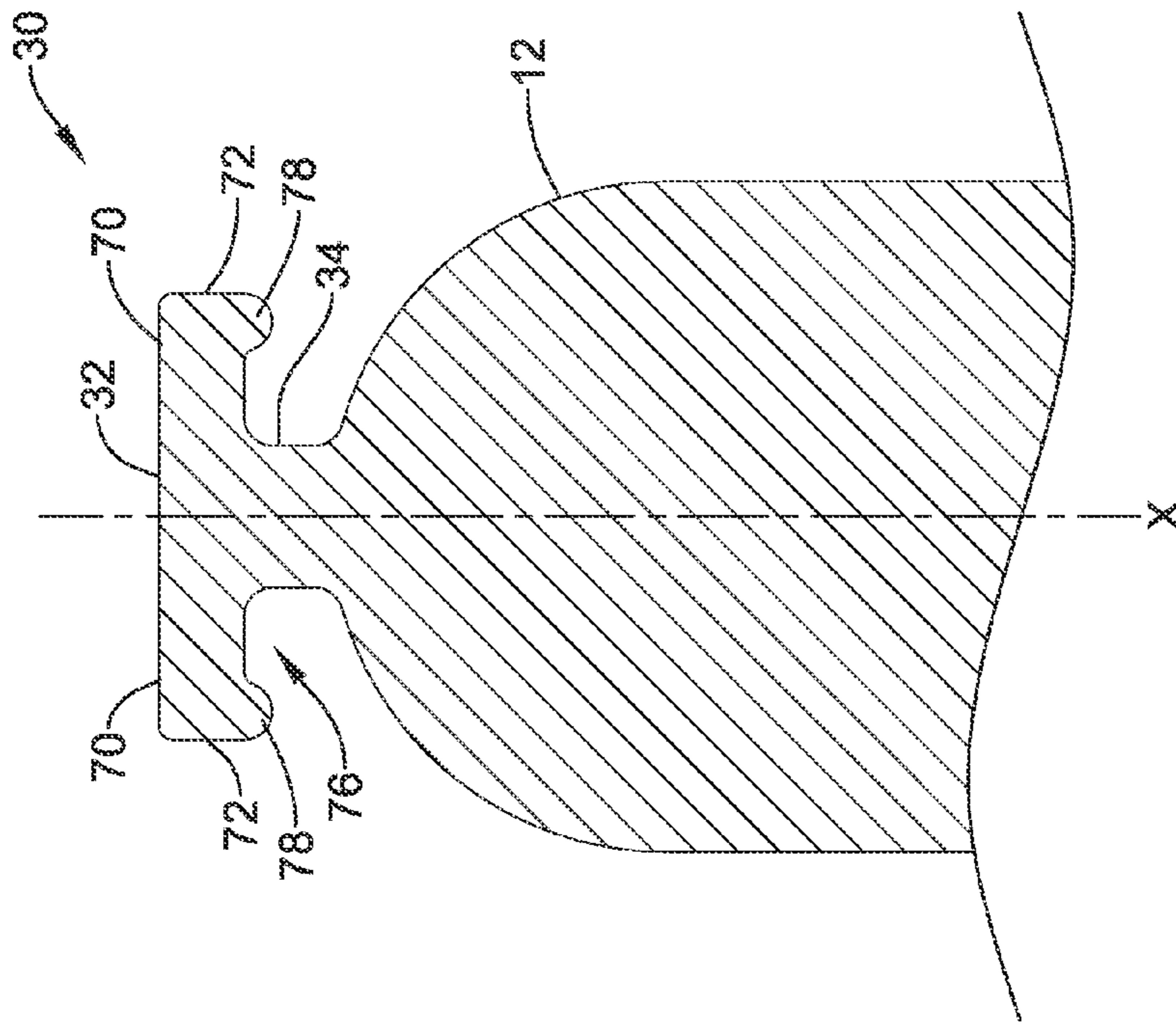


FIG. 14C

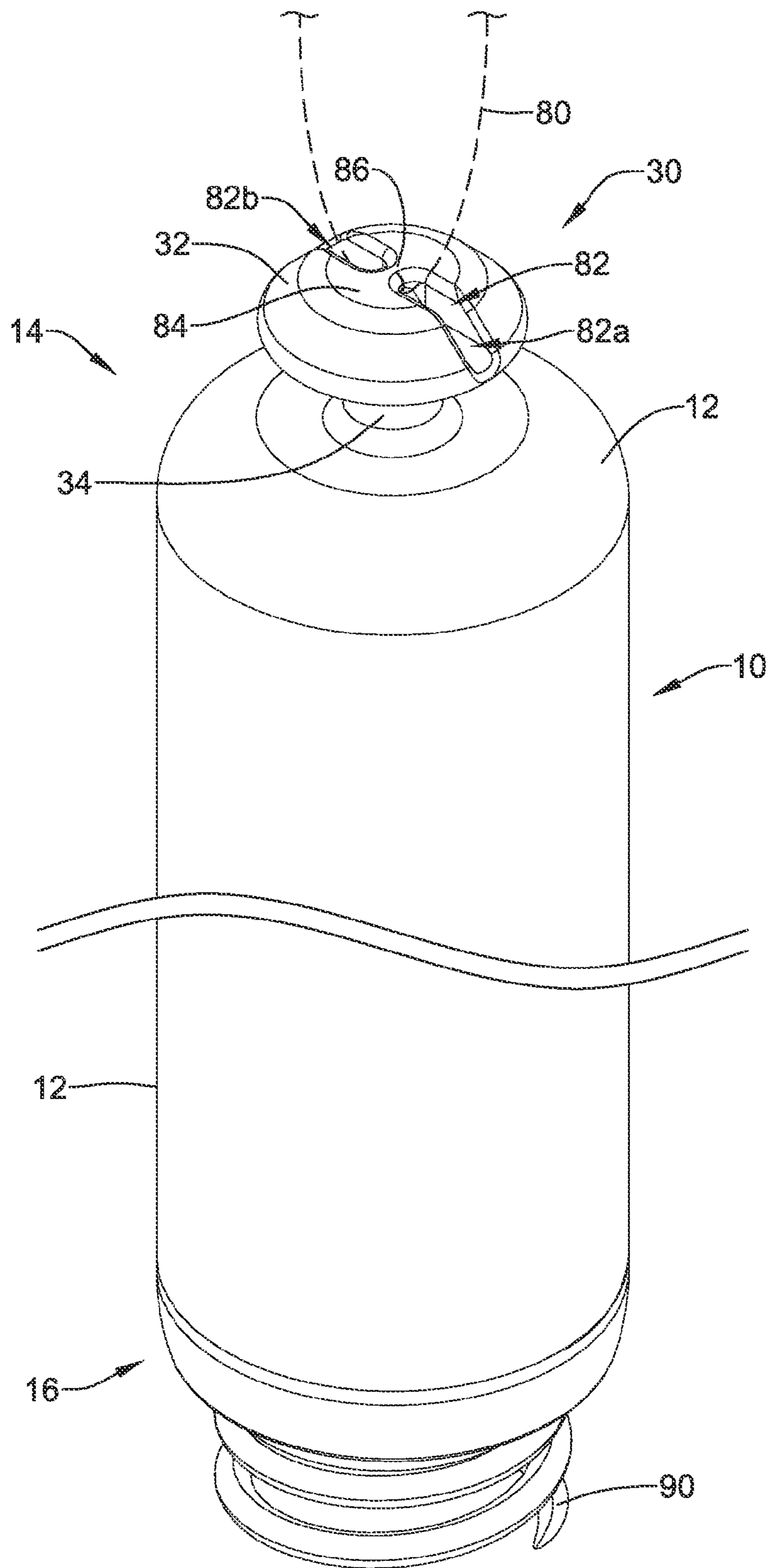


FIG. 15A

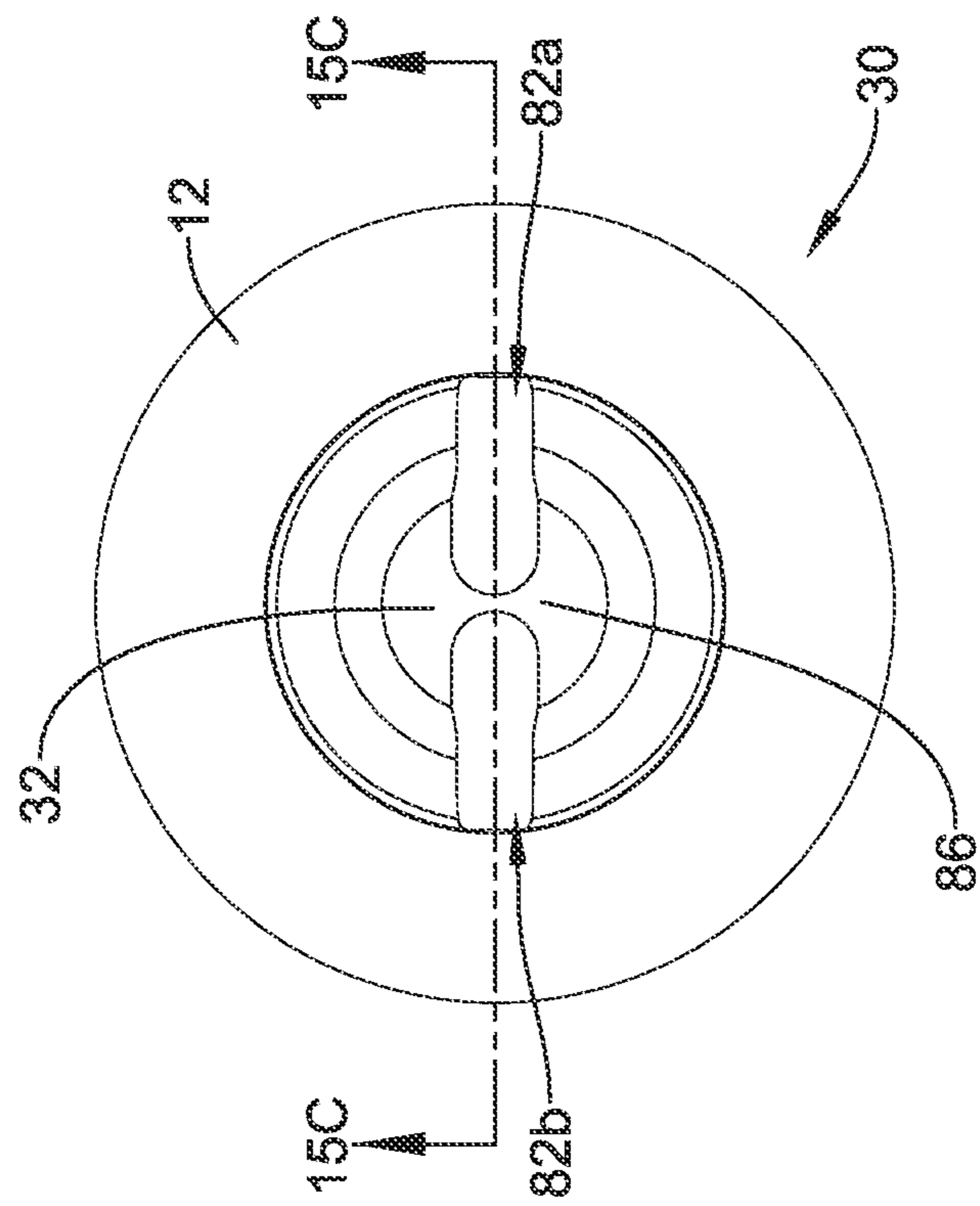


FIG. 15B

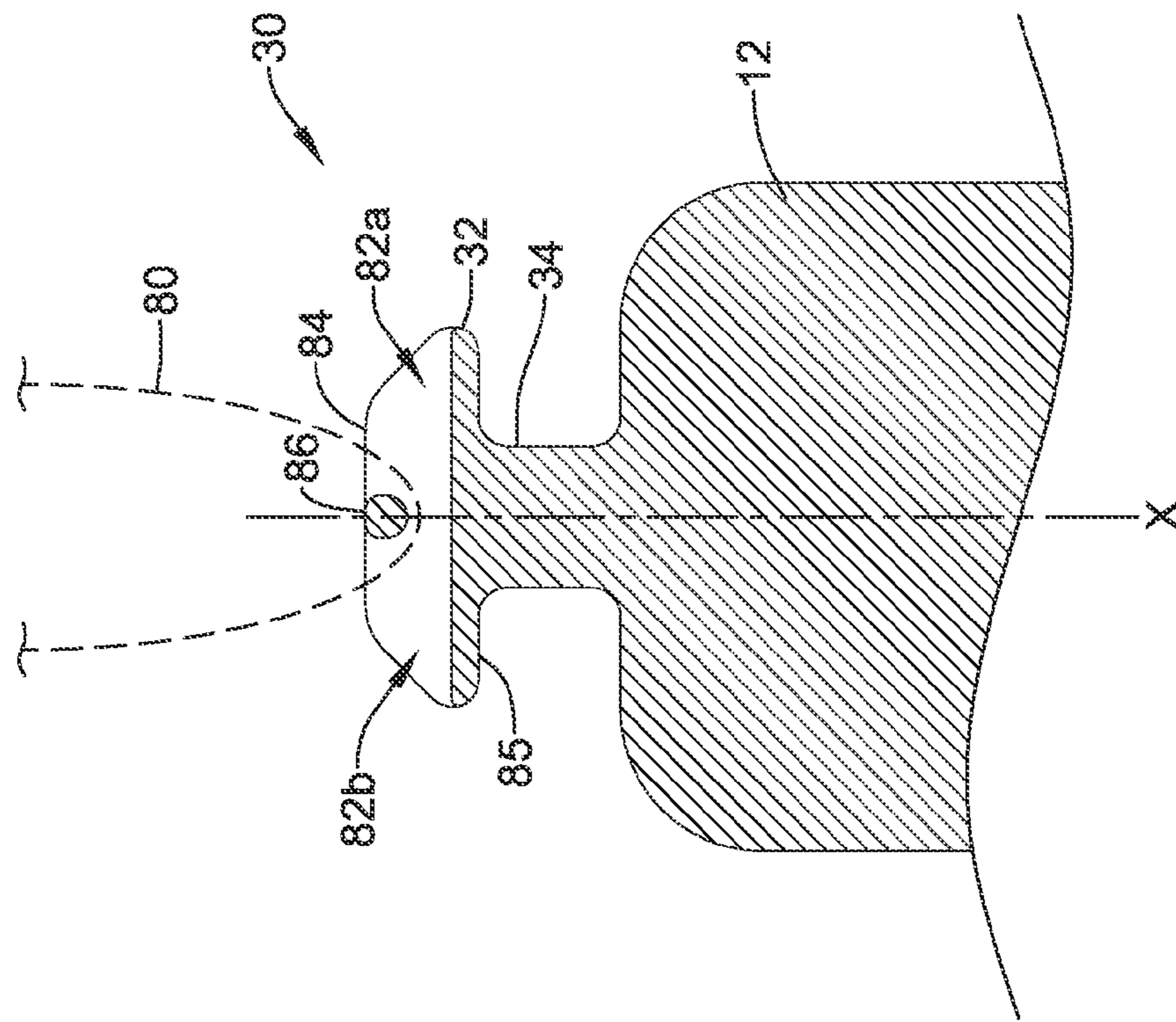


FIG. 15C

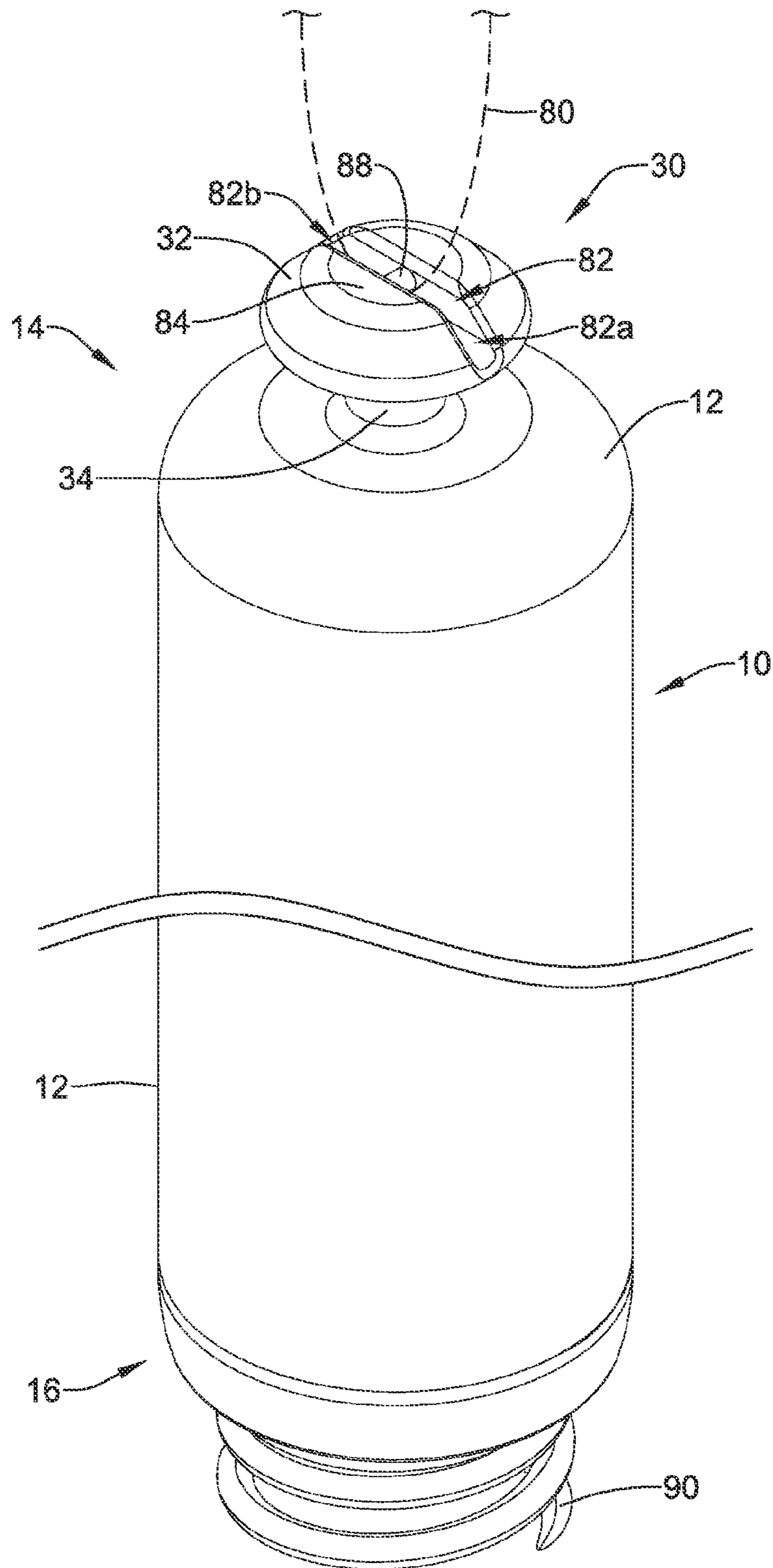


FIG. 16A

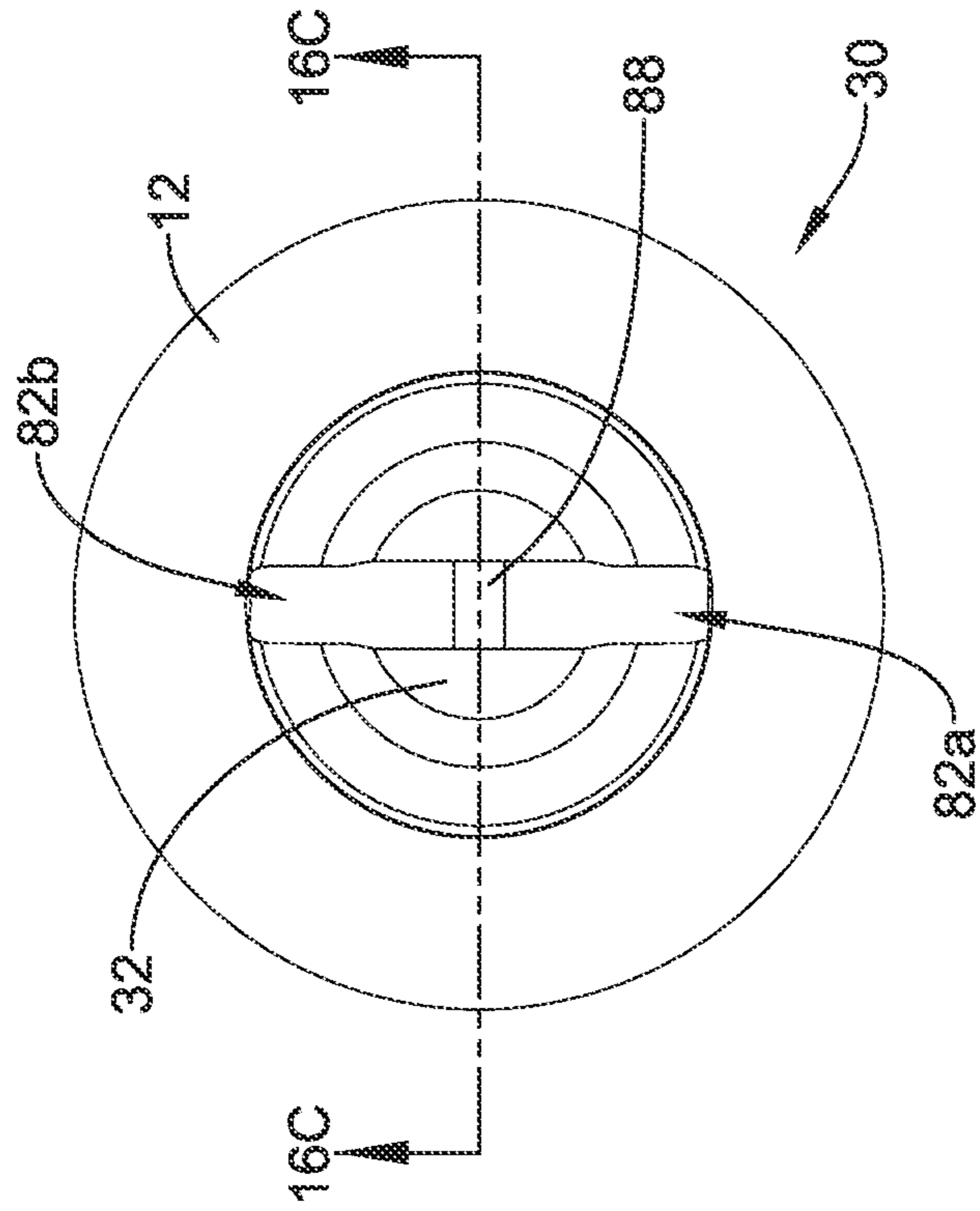


FIG. 16B

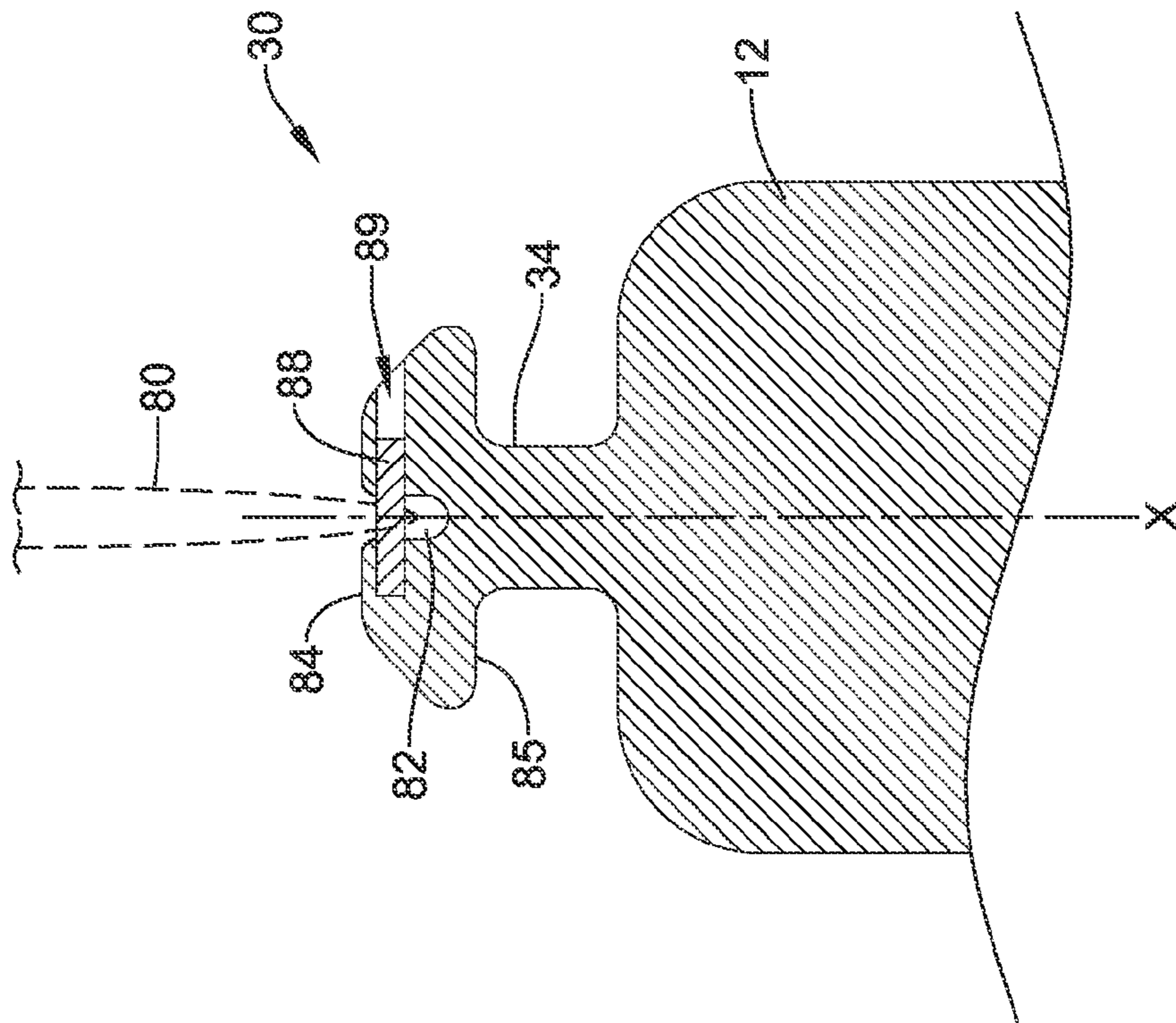


FIG. 16C

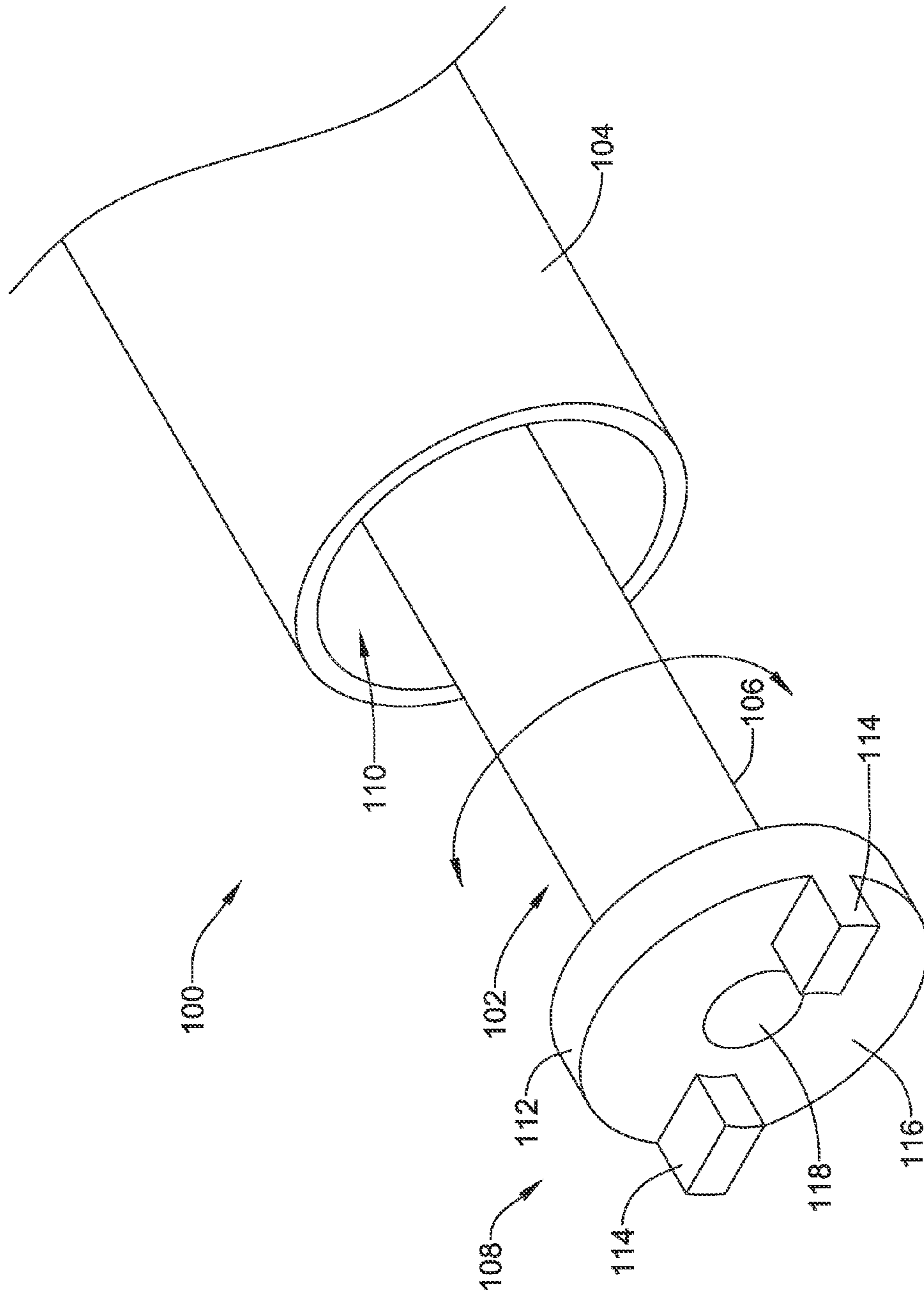


FIG. 17A

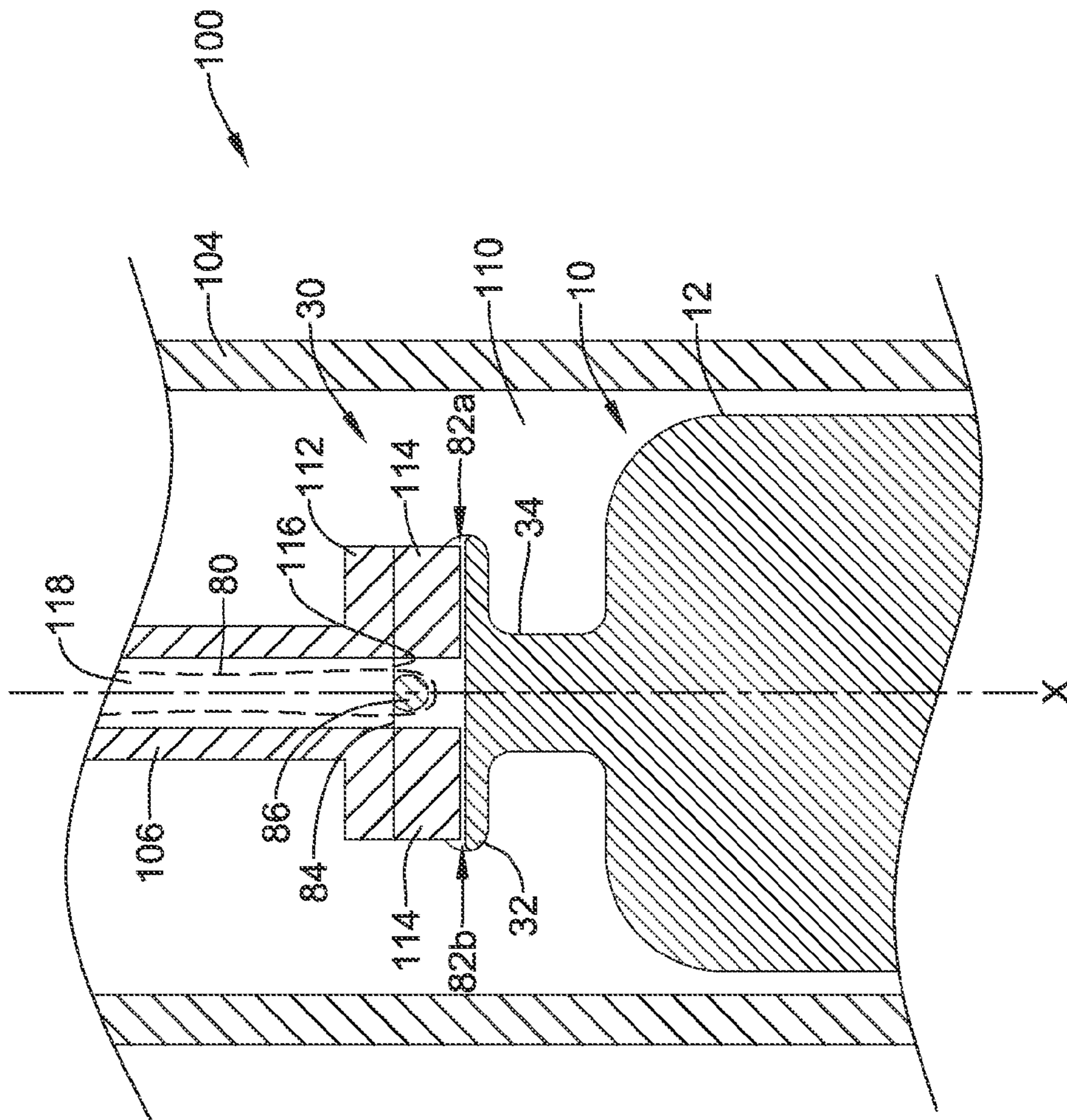


FIG. 17B

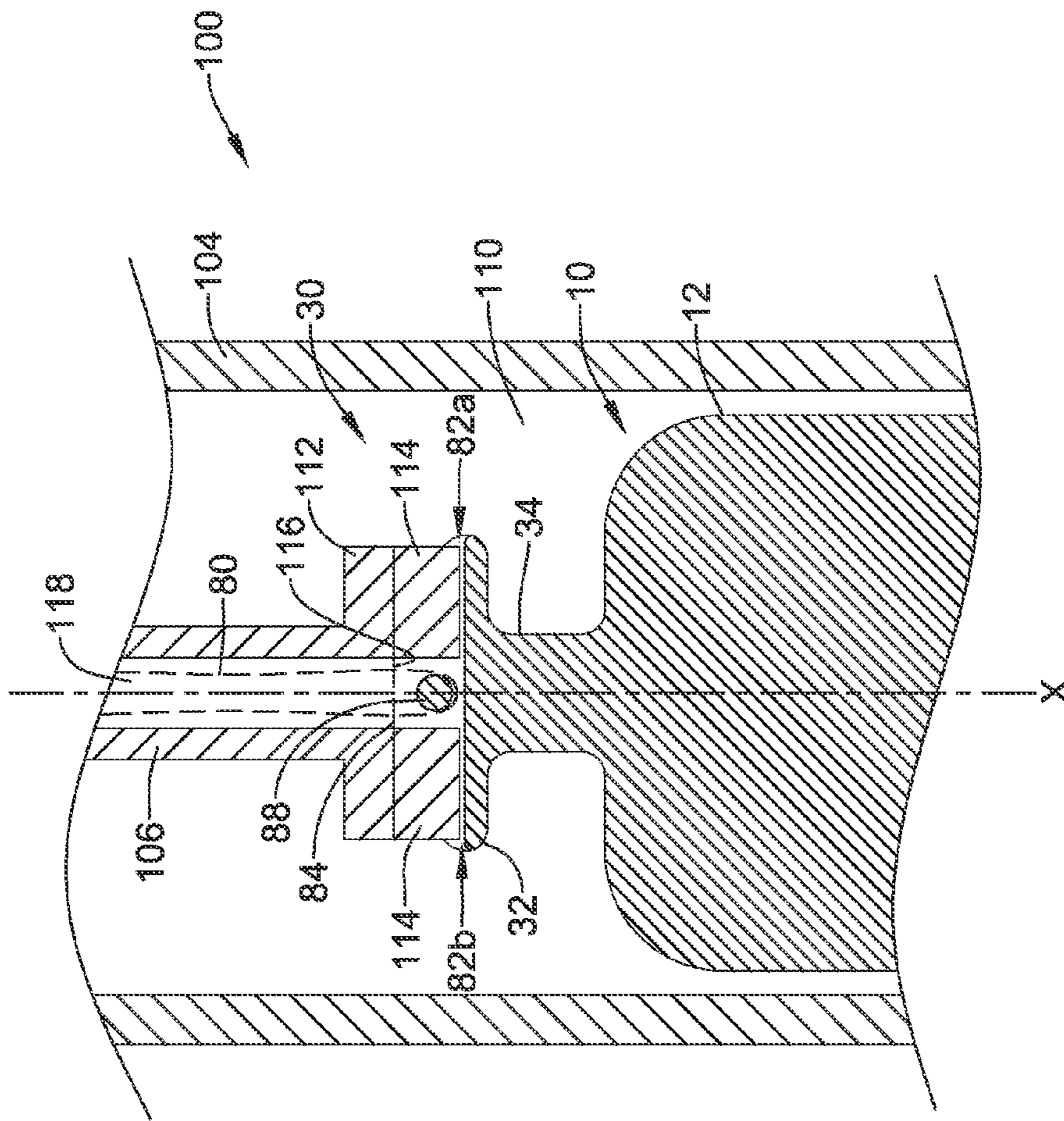


FIG. 17C

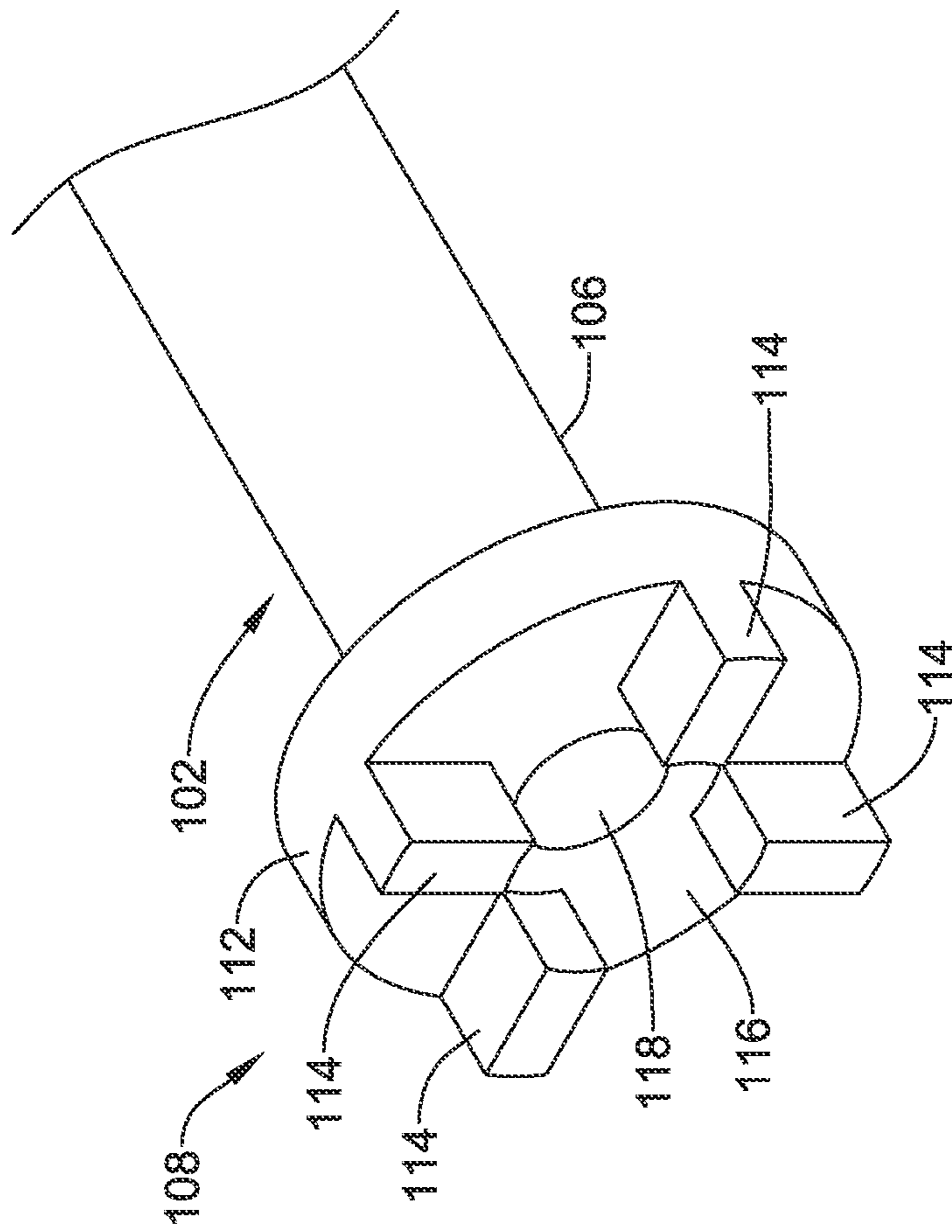


FIG. 18A

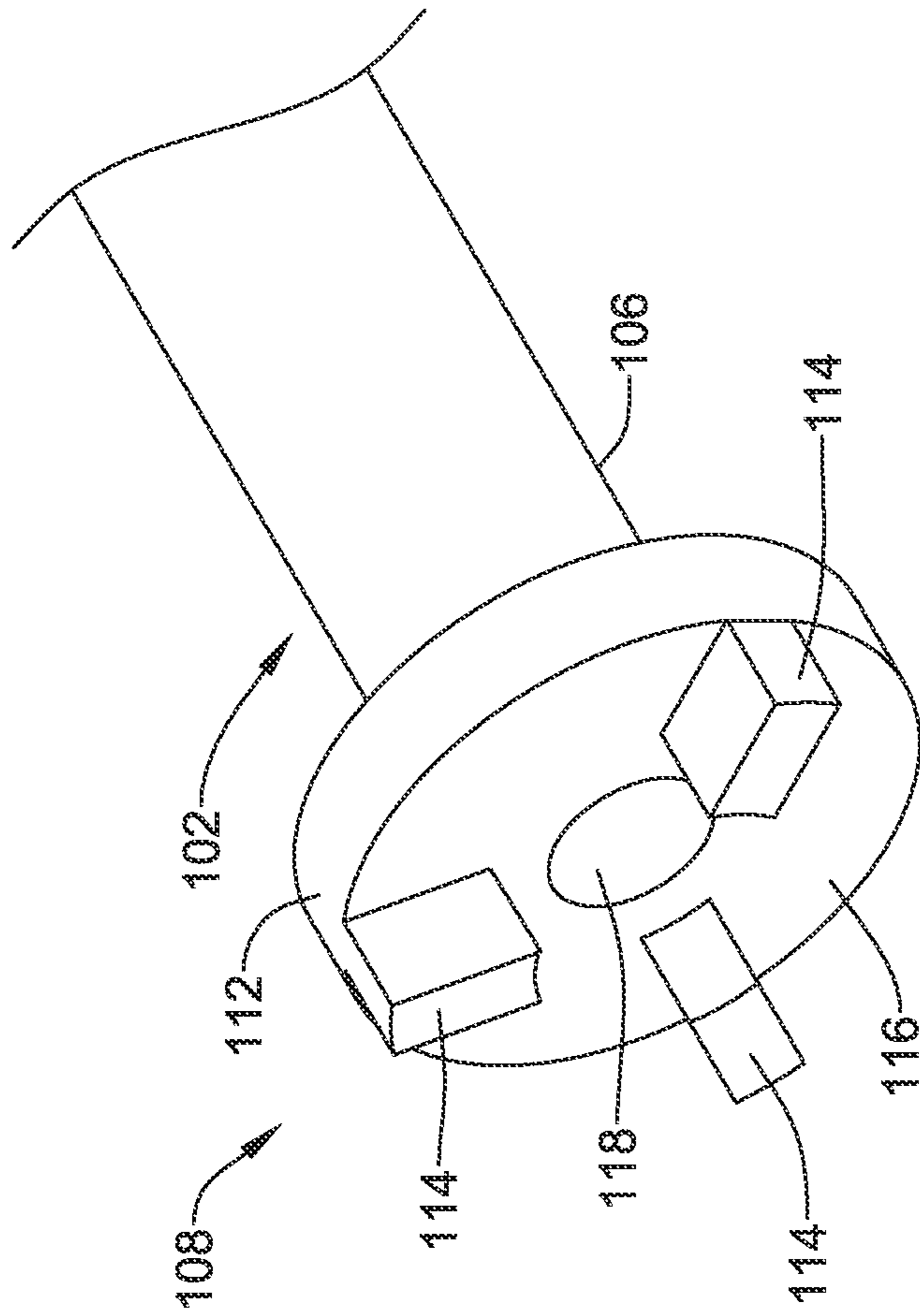


FIG. 18B

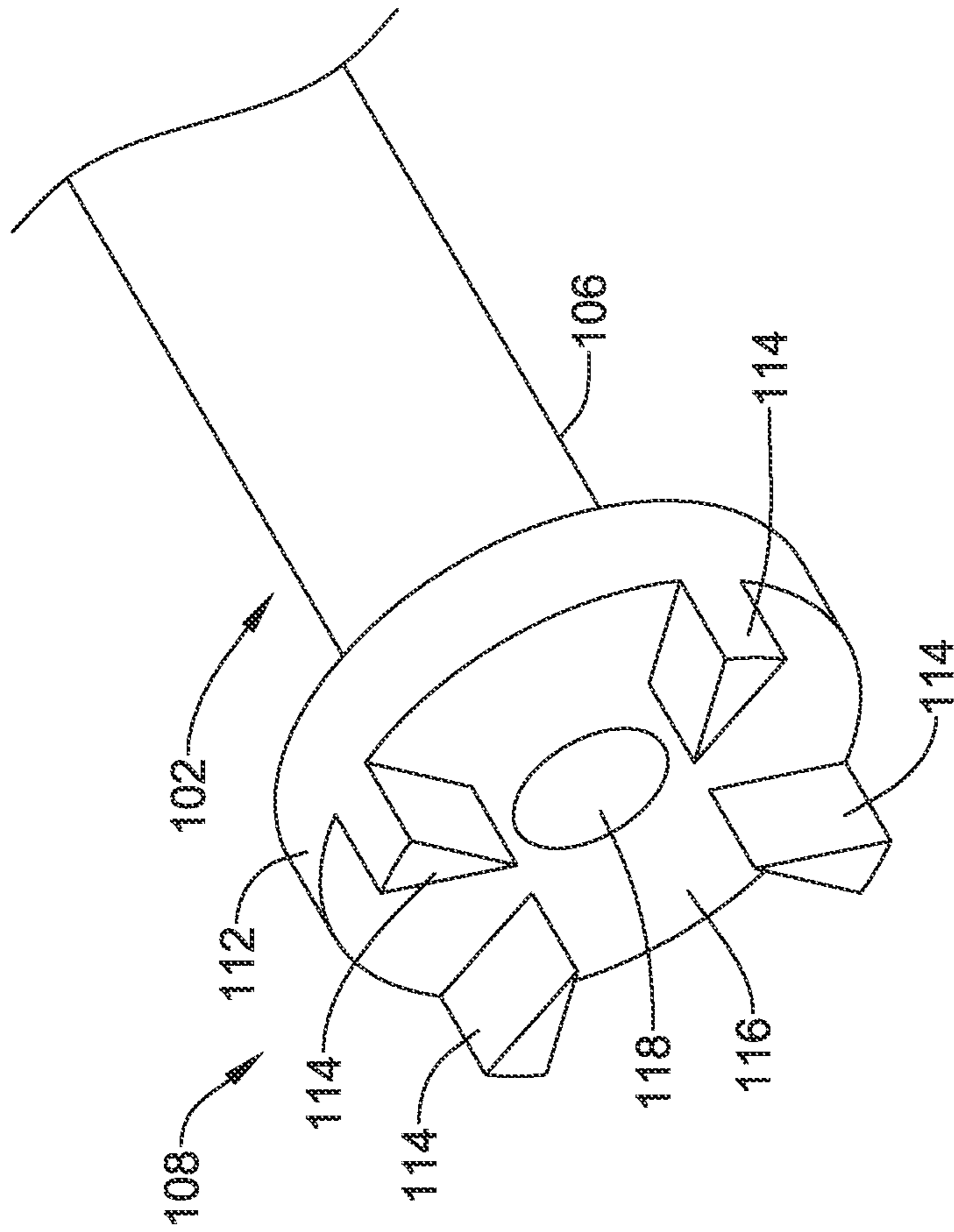


FIG. 18C

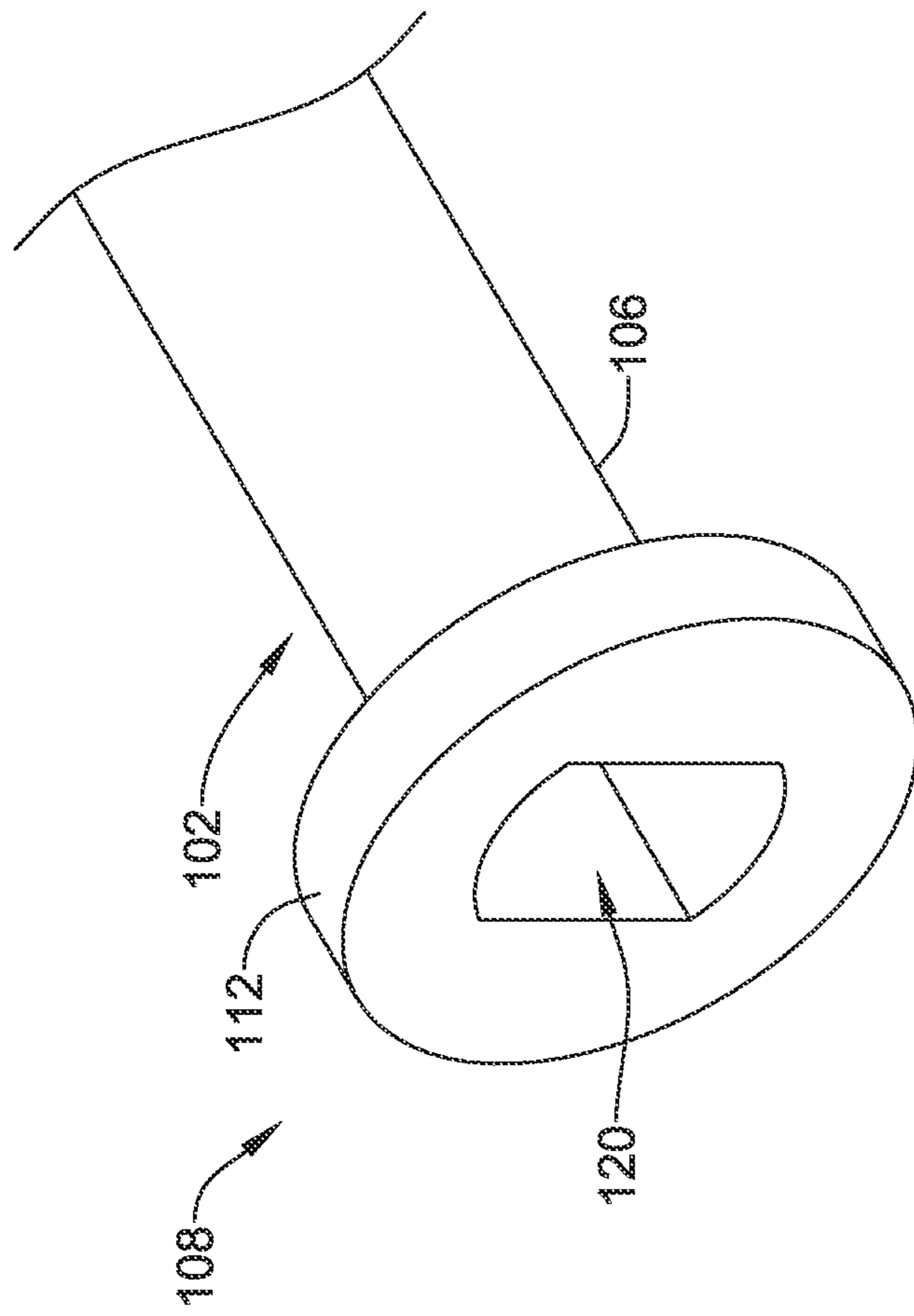


FIG. 18D

LEADLESS CARDIAC PACEMAKER WITH DELIVERY AND/OR RETRIEVAL FEATURES

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/866,644 filed Aug. 16, 2013, the complete disclosure of which is herein incorporated by reference.

TECHNICAL FIELD

The disclosure is directed to implantable cardiac devices. More particularly, the disclosure is directed to leadless cardiac stimulators or pacemakers including delivery and/or retrieval features.

BACKGROUND

Cardiac pacemakers provide electrical stimulation to heart tissue to cause the heart to contract and thus pump blood through the vascular system. Conventional pacemakers typically include an electrical lead that extends from a pulse generator implanted subcutaneously or sub-muscularly to an electrode positioned adjacent the inside or outside wall of the cardiac chamber. As an alternative to conventional pacemakers, self-contained or leadless cardiac pacemakers have been proposed. Leadless cardiac pacemakers are small capsules typically fixed to an intracardiac implant site in a cardiac chamber with a fixation mechanism engaging the intracardiac tissue. The small capsule typically includes bipolar pacing/sensing electrodes, a power source (e.g. a battery), and associated electrical circuitry for controlling the pacing/sensing electrodes, and thus provide electrical stimulation to heart tissue and/or sense a physiological condition.

Accordingly, there it is desirable to provide alternative structures to facilitate delivering leadless cardiac pacemakers to an implantation site in a heart chamber and/or retrieving leadless cardiac pacemakers from an implantation site in a heart chamber.

SUMMARY

The disclosure is directed to several alternative designs, materials and methods of manufacturing medical device structures and assemblies, and uses thereof.

Accordingly, one illustrative embodiment is an implantable leadless cardiac pacing device. The implantable device includes a housing, an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue, and a docking member extending from the proximal end of the housing along a longitudinal axis of the housing. The docking member is configured to facilitate retrieval of the implantable leadless cardiac pacing device. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The head portion has a radial dimension from the longitudinal axis and the neck portion has a radial dimension from the longitudinal axis less than the radial dimension of the head portion. The head portion includes a recess extending into the head portion from a proximal surface of the head portion for receiving a rotational driving instrument.

Another illustrative embodiment is an implantable leadless cardiac pacing device. The implantable device includes a housing, an electrode positioned proximate the distal end

of the housing configured to be positioned adjacent cardiac tissue, and a docking member extending from the proximal end of the housing along a longitudinal axis of the housing. The docking member is configured to facilitate retrieval of the implantable leadless cardiac pacing device. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The head portion has a radial dimension from the longitudinal axis and the neck portion has a radial dimension from the longitudinal axis less than the radial dimension of the head portion. The head portion includes a plurality of radially extending spokes extending radially outward from the longitudinal axis of the housing.

Another illustrative embodiment is a system for implanting an implantable leadless cardiac pacing device. The system includes an implantable cardiac pacing device and a delivery device. The implantable cardiac pacing device has a housing, an electrode positioned proximate a distal end of the housing, and a docking member extending from a proximal end of the housing opposite the distal end. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The delivery device includes an elongate shaft and a driver mechanism at a distal end of the elongate shaft. The driver mechanism is configured for engagement with the head portion of the docking member. The driver mechanism includes a first lug configured to engage a recess extending into the head portion from a proximal surface of the head portion. In some instances, the driver mechanism includes first and second spaced apart lugs configured to engage first and second portions of the recess, respectively, with a member extending across the recess positioned between the first and second lugs.

Another illustrative embodiment is a system for retrieving an implantable leadless cardiac pacing device. The system includes an implantable cardiac pacing device and a retrieval device. The implantable cardiac pacing device has a housing having a longitudinal axis, an electrode positioned proximate a distal end of the housing, and a docking member extending from a proximal end of the housing opposite the distal end. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The head portion includes a plurality of radially extending spokes extending radially outward from the longitudinal axis of the housing. The retrieval device includes a snare having an elongate shaft and one or more loops at a distal end of the elongate shaft. The one or more loops of the retrieval device are capable of encircling one or more of the radially extending spokes to capture the docking member with the snare.

Another illustrative embodiment is a method of implanting an implantable cardiac pacing device. The method includes advancing an implantable cardiac pacing device into a chamber of a heart with a delivery device. The implantable cardiac pacing device includes a helical fixation mechanism extending from a distal end of a housing of the implantable cardiac pacing device and a docking member extending from a proximal end of the housing. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The method further includes rotating an elongate shaft of the delivery device to rotate the helical fixation mechanism into cardiac tissue. The delivery device includes a driver mechanism at a distal end of the elongate shaft. The driver mechanism includes a first lug engaged in a recess of the head portion

of the docking member to transfer rotational motion from the driver mechanism to the implantable cardiac pacing device.

Yet another illustrative embodiment is a method of retrieving an implantable cardiac pacing device from a heart. The implantable cardiac pacing device has a housing having a longitudinal axis, an electrode positioned proximate a distal end of the housing, and a docking member extending from a proximal end of the housing opposite the distal end. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The head portion includes a plurality of radially extending spokes extending radially outward from the longitudinal axis of the housing. The method includes advancing a snare into a heart having the implantable cardiac pacing device implanted therein and encircling the docking member with a loop of the snare. The loop is then cinched around a portion of the docking member and the snare is actuated proximally to pull the implantable cardiac pacing device into a lumen of a retrieval catheter.

The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the aspects of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The aspects of the disclosure may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. 1 illustrates an exemplary implantable device implanted in a chamber of a heart;

FIG. 2 illustrates an exemplary retrieval device capturing an implantable device during a retrieval procedure;

FIG. 3 illustrates another exemplary retrieval device capturing an implantable device during a retrieval procedure;

FIGS. 4A-4C illustrate an exemplary docking member of an implantable device;

FIGS. 5A-5C illustrate another exemplary docking member of an implantable device;

FIGS. 6A-6C illustrate another exemplary docking member of an implantable device;

FIGS. 7A-7C illustrate another exemplary docking member of an implantable device;

FIGS. 8A-8C illustrate another exemplary docking member of an implantable device;

FIGS. 9A-9C illustrate another exemplary docking member of an implantable device;

FIGS. 10A-10C illustrate another exemplary docking member of an implantable device;

FIGS. 11A-11C illustrate another exemplary docking member of an implantable device;

FIGS. 12A-12C illustrate another exemplary docking member of an implantable device;

FIGS. 13A-13C illustrate another exemplary docking member of an implantable device;

FIGS. 14A-14C illustrate another exemplary docking member of an implantable device;

FIGS. 15A-15C illustrate another exemplary docking member of an implantable device;

FIGS. 16A-16C illustrate another exemplary docking member of an implantable device;

FIG. 17A illustrates an exemplary delivery device for delivering an implantable device;

FIG. 17B illustrates the delivery device of FIG. 17A in engagement with the docking member of the implantable device of FIGS. 15A-15C;

FIG. 17C illustrates the delivery device of FIG. 17A in engagement with the docking member of the implantable device of FIGS. 16A-16C; and

FIGS. 18A-18D illustrate alternative embodiments of a driver mechanism for a rotational driving instrument.

While the aspects of the disclosure are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term “about”, whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the term “about” may be indicative as including numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

Although some suitable dimensions, ranges and/or values pertaining to various components, features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges and/or values may deviate from those expressly disclosed.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment unless clearly stated to the contrary.

Referring to FIG. 1, an exemplary implantable leadless cardiac pacing device 10 (e.g., a leadless pacemaker) is illustrated implanted in a chamber of a heart H, such as the apex of the right ventricle RV. The implantable device 10 may include a shell or housing 12 having a proximal end 14 and a distal end 16. The implantable device 10 may include a first electrode 20 positioned proximate the distal end 16 of the housing 12 and a second electrode 22 positioned proximate the proximal end 14 of the housing 12. The electrodes 20, 22 may be sensing and/or pacing electrodes to provide electro-therapy and/or sensing capabilities. The first electrode 20 may be configured to be positioned against or otherwise contact the cardiac tissue of the heart H while the second electrode 22 may be spaced away from the first electrode 20, and thus spaced away from the cardiac tissue.

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The implantable device **10** may include a pulse generator (e.g., electrical circuitry) and a power source (e.g., a battery) within the housing **12** to provide electrical signals to the electrodes **20**, **22** and thus control the pacing/sensing electrodes **20**, **22**. Electrical communication between pulse generator and the electrodes **20**, **22** may provide electrical stimulation to heart tissue and/or sense a physiological condition.

The implantable device **10** may include a fixation mechanism **24** proximate the distal end **16** of the housing **12** configured to attach the implantable device **10** to a tissue wall of the heart H, or otherwise anchor the implantable device **10** to the anatomy of the patient. As shown in FIG. **1**, in some instances, the fixation mechanism **24** may include one or more, or a plurality of hooks **26** anchored into the cardiac tissue of the heart H to attach the implantable device **10** to a tissue wall. In other instances, the fixation mechanism **24** may include one or more, or a plurality of passive tines, configured to entangle with trabeculae within the chamber of the heart H and/or a helical fixation anchor configured to be screwed into a tissue wall to anchor the implantable device **10** to the heart H.

The implantable device **10** may include a docking member **30** proximate the proximal end **14** of the housing **12** configured to facilitate delivery and/or retrieval of the implantable device **10**. For example, the docking member **30** may extend from the proximal end **14** of the housing **12** along a longitudinal axis of the housing **12**. The docking member **30** may include a head portion **32** and a neck portion **34** extending between the housing **12** and the head portion **32**. The head portion **32** may be an enlarged portion relative to the neck portion **34**. For example, the head portion **32** may have a radial dimension from the longitudinal axis of the implantable device **10** which is greater than a radial dimension of the neck portion from the longitudinal axis of the implantable device **10**. The docking member **30** may be configured to facilitate delivery of the implantable device **10** to the intracardiac site and/or retrieval of the implantable device **10** from the intracardiac site. Some exemplary embodiments of the docking member **30** are described in further detail herein.

If it is desired to retrieve the implantable device **10** from the heart H, a retrieval device **50** may be advanced into the chamber of the heart H to capture the implantable device **10** and remove the implantable device **10** from the heart H. One exemplary retrieval device **50** is illustrated in FIG. **2**. The retrieval device **50** may include a snare **52** advanceable from a lumen **58** of a retrieval catheter **54**. The snare **52** may include one or more, or a plurality of loops **56** extending from a distal end of the snare **52** configured to engage the docking member **30** of the implantable device **10**. The snare **52** shown in FIG. **2** includes three loops **56** formed by elongate filaments extending from the shaft of the snare **52**. Once the loop(s) **56** of the snare **52** has captured the docking member **30**, the snare **52** may be actuated proximally relative to the retrieval catheter **54** to pull the implantable device **10** into the lumen **58** of the retrieval catheter **54**. The enlarged size of the head portion **32** relative to the neck portion **34** may permit the loop **56** of the snare **52** to encircle the neck portion **34** below (i.e., distal of) the head portion **32** and retain the loop **56** around the docking member **30** as the snare **52** is pulled proximally. As the implantable device **10** is pulled into the retrieval catheter **54**, the fixation mechanism **24** may disengage from the heart tissue to detach the implantable device **10** from the heart wall. For example, the hooks **26** may elongate as the implantable device **10** is drawn proximally into the lumen **58** of the retrieval catheter

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54. Thereafter, the retrieval device **50**, with the implantable device **10** captured in the lumen of the retrieval catheter **54** with the snare **52**, may be withdrawn from the heart H.

Another exemplary retrieval device **50** is illustrated in FIG. **3**. Similar to FIG. **2**, the retrieval device **50** may include a snare **52** advanceable from a lumen **58** of a retrieval catheter **54**. The snare **52** may include one or more, or a plurality of loops **56** extending from a distal end of the snare **52** configured to engage the docking member **30** of the implantable device **10**. The snare **52** shown in FIG. **3** includes a single loop **56** formed by an elongate filament extending from the shaft of the snare **52**. Once the loop **56** of the snare **52** has captured the docking member **30**, the snare **52** may be actuated proximally relative to the retrieval catheter **54** to pull the implantable device **10** into the lumen **58** of the retrieval catheter **54**. The enlarged size of the head portion **32** relative to the neck portion **34** may permit the loop **56** of the snare **52** to encircle the neck portion **34** below (i.e., distal of) the head portion **32** and retain the loop **56** around the docking member **30** as the snare **52** is pulled proximally. As the implantable device **10** is pulled into the retrieval catheter **54**, the fixation mechanism **30** may disengage from the heart tissue to detach the implantable device **10** from the heart wall. For example, the hooks **26** may elongate as the implantable device **10** is drawn proximally into the lumen **58** of the retrieval catheter **54**. Thereafter, the retrieval device **50**, with the implantable device **10** captured in the lumen of the retrieval catheter **54** with the snare **52**, may be withdrawn from the heart H.

FIGS. **4A-4C** illustrate one exemplary docking member **30** located at the proximal end **14** of the implantable device **10**. The docking member **30** shown in FIGS. **4A-4C** may include a head portion **32** and a neck portion **34** extending between the housing **12** and the head portion **32**. The head portion **32** may be a generally spherically shaped ball, having a diameter **D1** greater than the diameter **D2** of the neck portion **34**. The docking member **30** may also include a passage **36** extending through a portion of the docking member **30** to receive a tether **80** (shown in phantom lines) which will be further described later herein. For example, the passage **36** may extend through the head portion **32** from a first side to a second side of the head portion **32**. The spherical shape of the head portion **32** may provide an atraumatic profile, inhibiting tissue growth or entanglement around the docking member **30**.

FIGS. **5A-5C** illustrate another exemplary docking member **30** located at the proximal end **14** of the implantable device **10**. The docking member **30** shown in FIGS. **5A-5C** may include a head portion **32** and a neck portion **34** extending between the housing **12** and the head portion **32**. The head portion **32** may be a generally disc shaped element having an upper surface **62** and an opposing lower surface **64**. In some instances, the upper surface **62** and/or the lower surface **64** may be a spherically convex surface while in other instances the upper surface **62** and/or the lower surface **64** may be a spherically concave surface or a planar surface, for example. The head portion **32** may have a diameter **D1** greater than the diameter **D2** of the neck portion **34**. Although not shown, the docking member **30** may also include a passage extending through a portion of the docking member **30** to receive a tether (described later herein). For example, a passage may extend through the head portion **32** from a first side to a second side of the head portion **32**, or a passage may extend through the neck portion **34** from a first side to a second side of the neck portion **34**. The shape

of the head portion 32 may provide an atraumatic profile, inhibiting tissue growth or entanglement around the docking member 30.

FIGS. 6A-6C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10. The docking member 30 shown in FIGS. 6A-6C may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may be generally knob shaped, having a diameter D1 greater than the diameter D2 of the neck portion 34. The docking member 30 may also include a passage 36 extending through a portion of the docking member 30 to receive a tether 80 (shown in phantom) further described later herein. For example, the head portion 32 may include a central opening 66 extending into the head portion 32. A pin 68 may extend into or across the opening 66. For example, as shown in FIG. 6C the pin 68 may extend from a first side to a second side of the opening 66. In other instances, the pin 68 may extend into the opening 66 from a first side toward a second side of the opening 66, but not entirely across the opening 66 to the second side. The passage 36 may extend under the pin 68 such that the tether may be passed around the pin 68. The shape of the head portion 32 may provide an atraumatic profile, inhibiting tissue growth or entanglement around the docking member 30.

FIGS. 7A-7C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10. The docking member 30 shown in FIGS. 7A-7C may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may include a plurality of enlarged portions 70 spaced apart by a reduced diameter necked portion 72. In some instances, the enlarged portions 70 may be generally knob shaped, having a diameter D1 greater than the diameter D3 of the necked portion between the enlarged portions 70 and the diameter D2 of the neck portion 34. Multiple enlarged portions 70 may facilitate engaging the docking member 30 with the loop(s) 56 of the snare 52 during retrieval of the implantable device 10. The shape of the head portion 32 may provide an atraumatic profile, inhibiting tissue growth or entanglement around the docking member 30.

The docking member 30 may also include a passage 36 extending through a portion of the docking member 30 to receive a tether (described later herein). For example, the head portion 32 may include a central opening 66 extending into the head portion 32. A pin 68 may extend into or across the opening 66. For example, as shown in FIG. 7C the pin 68 may extend from a first side to a second side of the opening 66. In other instances, the pin 68 may extend into the opening 66 from a first side toward a second side of the opening 66, but not entirely across the opening 66 to the second side. The passage 36 may extend under the pin 68 such that the tether may be passed around the pin 68.

FIGS. 8A-8C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10. The docking member 30 shown in FIGS. 8A-8C may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may have a diameter D1 greater than the diameter D2 of the neck portion 34. The head portion 32 may include a plurality of spokes 70 extending radially from the longitudinal axis of the implantable device 10, with spaces defined between adjacent spokes 70. The spokes 70 may be symmetrically or asymmetrically arranged around the longitudinal axis X. For example, the head portion 32

may include four spokes 70 uniformly arranged around the longitudinal axis X about 90 degrees apart. As shown in FIG. 8X, the free ends 72 of the radially extending spokes 70 may angle (e.g., curve) toward the distal end 16 of the implantable device 10, in some instances. For example, an upper surface 74 and/or a lower surface 76 of the spokes 70 may extend at an oblique angle to the longitudinal axis X of the implantable device 10 toward the distal end 16, such that the free ends 72 of the spokes 70 are positioned closer to the distal end 16 of the implantable device 10 than the base portion of the spokes 70 proximate the central longitudinal axis X. The configuration and/or arrangement of the spokes 70 may facilitate retention of the loop 56 of the snare 52 in engagement of the docking member 30 during retrieval of the implantable device 10. For example, the loop 56 may encircle one or more of the spokes 70 in addition to or instead of the neck portion 34.

Although not shown, the docking member 30 may also include a passage extending through a portion of the docking member 30 to receive a tether (described later herein). For example, a passage may extend through the one or more of the spokes 70 from a first side to a second side of the spoke 70, or a passage may extend through the neck portion 34 from a first side to a second side of the neck portion 34.

FIGS. 9A-9C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10, similar to the docking member 30 illustrated in FIGS. 8A-8C. The docking member 30 shown in FIGS. 9A-9C may similarly include a plurality of spokes 70 extending radially from the longitudinal axis of the implantable device 10, with spaces defined between adjacent spokes 70, except the spokes 70 shown in FIGS. 9A-9C may have a width W less than the width of the spokes shown in FIGS. 8A-8C.

Although not shown, the docking member 30 may also include a passage extending through a portion of the docking member 30 to receive a tether (described later herein). For example, a passage may extend through the one or more of the spokes 70 from a first side to a second side of the spoke 70, or a passage may extend through the neck portion 34 from a first side to a second side of the neck portion 34.

FIGS. 10A-10C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10, similar to the docking member 30 illustrated in FIGS. 8A-8C. The docking member 30 shown in FIGS. 10A-10C may similarly include a plurality of spokes 70 extending radially from the longitudinal axis of the implantable device 10, with spaces defined between adjacent spokes 70. The width W of the spokes 70 shown in FIGS. 10A-10C may increase from the base portion toward the free ends 72 of the spokes. Thus, in instances in which the loop 56 of the snare 52 encircles one or more of the spokes 70, the enlarged free end 72 of the spokes 70 may prevent the loop 56 of the snare 52 from slipping off the spoke(s) 70 during retrieval of the implantable device 10.

Although not shown, the docking member 30 may also include a passage extending through a portion of the docking member 30 to receive a tether (described later herein). For example, a passage may extend through the one or more of the spokes 70 from a first side to a second side of the spoke 70, or a passage may extend through the neck portion 34 from a first side to a second side of the neck portion 34.

FIGS. 11A-11C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10, similar to the docking member 30 illustrated in FIGS. 8A-8C. The docking member 30 shown in FIGS. 11A-11C may include a pair of spokes 70 extending radially

from the longitudinal axis of the implantable device 10 in opposite directions. Similar to the spokes 70 shown in FIGS. 10A-10C, the width W of the spokes 70 shown in FIGS. 11A-11C may increase from the base portion toward the free ends 72 of the spokes. Thus, in instances in which the loop 56 of the snare 52 encircles one or more of the spokes 70, the enlarged free end 72 of the spokes 70 may prevent the loop 56 of the snare 52 from slipping off the spoke(s) 70 during retrieval of the implantable device 10.

Although not shown, the docking member 30 may also include a passage extending through a portion of the docking member 30 to receive a tether (described later herein). For example, a passage may extend through the one or more of the spokes 70 from a first side to a second side of the spoke 70, or a passage may extend through the neck portion 34 from a first side to a second side of the neck portion 34.

FIGS. 12A-12C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10, similar to the docking member 30 illustrated in FIGS. 11A-11C. The docking member 30 shown in FIGS. 12A-12C may include a pair of spokes 70 extending radially from the longitudinal axis of the implantable device 10 in opposite directions. The free ends 72 of the spokes 70 may include a crossing member 74 extending transverse to the radial direction of the spokes 70. In some instances, the crossing member 74 may extend in opposite directions from the body of the spoke 70, or the crossing member 74 may extend in one transverse direction from the body of the spoke 70. For example, in some instances, the spokes 70 may have a T shape, a mushroom shape, an L shape, a V shape, or other desired shape. In some instances, the crossing member 74 may form an undercut 76 with the body of the spoke 70. The loop 56 of the snare 52 may be engaged in the undercuts 76 as the loop 56 is tightened around the spoke 70. In instances in which the loop 56 of the snare 52 encircles one or more of the spokes 70, the crossing member 74 at the free end 72 of the spokes 70 may prevent the loop 56 of the snare 52 from slipping off the spoke(s) 70 during retrieval of the implantable device 10.

Although not shown, the docking member 30 may also include a passage extending through a portion of the docking member 30 to receive a tether (described later herein). For example, a passage may extend through the one or more of the spokes 70 from a first side to a second side of the spoke 70, or a passage may extend through the neck portion 34 from a first side to a second side of the neck portion 34.

FIGS. 13A-13C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10, similar to the docking member 30 illustrated in FIGS. 12A-12C. The docking member 30 shown in FIGS. 13A-13C may include a plurality of spokes 70 extending radially from the longitudinal axis of the implantable device 10, with spaces defined between adjacent spokes 70. The spokes 70 may be symmetrically or asymmetrically arranged around the longitudinal axis. For example, the head portion 32 may include three spokes 70 uniformly arranged around the longitudinal axis about 120 degrees apart. Similar to the spokes illustrated in FIGS. 12A-12C, the free ends 72 of the spokes 70 may include a crossing member 74 extending transverse to the radial direction of the spokes 70. In some instances, the crossing member 74 may extend in opposite directions from the body of the spoke 70, or the crossing member 74 may extend in one transverse direction from the body of the spoke 70. For example, in some instances, the spokes 70 may have a T shape, a mushroom shape, an L shape, a V shape, or other desired shape. In some instances, the crossing member 74 may form an undercut 76 with the

body of the spoke 70. The loop 56 of the snare 52 may be engaged in the undercuts 76 as the loop 56 is tightened around the spoke 70. In instances in which the loop 56 of the snare 52 encircles one or more of the spokes 70, the crossing member 74 at the free end 72 of the spokes 70 may prevent the loop 56 of the snare 52 from slipping off the spoke(s) 70 during retrieval of the implantable device 10.

Although not shown, the docking member 30 may also include a passage extending through a portion of the docking member 30 to receive a tether (described later herein). For example, a passage may extend through the one or more of the spokes 70 from a first side to a second side of the spoke 70, or a passage may extend through the neck portion 34 from a first side to a second side of the neck portion 34.

FIGS. 14A-14C illustrate another exemplary docking member 30 located at the proximal end 14 of the implantable device 10, similar to the docking member 30 illustrated in FIGS. 8A-8C. The docking member 30 shown in FIGS. 14A-14C may similarly include a plurality of spokes 70 extending radially from the longitudinal axis of the implantable device 10, with spaces defined between adjacent spokes 70. The docking member 30 may include any number of radially extending spokes 70 symmetrically or asymmetrically arranged around the longitudinal axis of the implantable device 10. For example, the docking member 30 may include 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or more radially extending spokes 70 in some instances.

As shown in FIG. 14C, the free ends 72 of the spokes 70 may include a distally projecting lip 78 relative to the body portion of the spokes 70. The distally projecting lips 78 may prevent the loop 56 of the snare 52 from slipping off the spoke(s) 70 during retrieval of the implantable device 10.

The configuration and/or arrangement of the spokes 70 may facilitate retention of the loop 56 of the snare 52 in engagement of the docking member 30 during retrieval of the implantable device 10. For example, the loop 56 may encircle one or more of the spokes 70 in addition to or instead of the neck portion 34.

In some instances it may be desirable to apply rotational motion to the implantable device 10 during delivery and/or retrieval of the implantable device 10. For example, in some embodiments such as the embodiment shown in FIG. 15A, the implantable device 10 may include a helical fixation anchor 90 at the distal end 16 of the housing 12 configured to be screwed into a tissue wall through rotational motion of the implantable device 10 to anchor the implantable device 10 to the heart H. In such instances, the docking member 30 may include an engagement feature configured to mate with an engagement feature of a delivery device to transfer rotational motion from a rotatable shaft of the delivery device to the implantable device 10.

For example, in the embodiment of FIGS. 15A-15C, the implantable device 10 may include a docking member 30 extending from the proximal end 14 of the housing 12 along a longitudinal axis of the housing 12. The docking member 30 may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may be an enlarged portion relative to the neck portion 34. For example, the head portion 32 may have a radial dimension from the longitudinal axis of the implantable device 10 which is greater than a radial dimension of the neck portion from the longitudinal axis of the implantable device 10.

The head portion 32 may include a recess 82 extending into the head portion 32 from a proximal surface 84 of the head portion 32. The recess 82 may be configured to receive a rotational driving instrument therein. For example, the

recess 82 may be configured to receive a distal driver mechanism of a rotational driving instrument therein. In some instances, the recess 82 may extend generally perpendicular to the longitudinal axis of the housing 12. In some embodiments, the recess 82 may extend across the head portion 32 from a first side of the head portion 32 to a second side of the head portion 32. As shown in FIG. 15C, the head portion 32 may include a distal surface 85 opposite the proximal surface 84 from which the neck portion 34 extends from. In some instances, the recess 82 may extend into the head portion 32 from the proximal surface 84 toward the distal surface 85, but does not extend to the distal surface 85. However, in other embodiments the recess 82 may extend to the distal surface 85.

The head portion 32 may also include a member 86 extending across the recess 82 dividing the recess 82 into a first recess portion 82a on a first side of the member 86 and a second recess portion 82b on a second side of the member 86. In some instances, the member 86 may extend generally perpendicular to the recess 82 and/or the longitudinal axis of the housing 12. As shown in FIGS. 15A-15C, in some instances the member 86 may be formed as a monolithic portion of the head portion 32 bridging across the recess 82. In other embodiments, however, the member 86 may be a separate component attached to the head portion 32.

A tether 80 may extend through a passage beneath the member 86 defined by the recess 82 during delivery of the implantable device 10. For example, the tether 80 may be attached to the member 86 and extend proximally from the member 86 along an elongate shaft of a delivery device to a location accessible by a physician during implantation of the implantable device 10. Once the implantable device 10 has been properly implanted in the heart H, the tether 80 may be detached from the member 86 and withdrawn from the patient.

FIGS. 16A-16C illustrate another implantable device 10 including a helical fixation anchor 90 at the distal end 16 of the housing 12 configured to be screwed into a tissue wall through rotational motion of the implantable device 10 to anchor the implantable device 10 to the heart H. Similar to the embodiment of FIGS. 15A-15C, the docking member 30 may include an engagement feature configured to mate with an engagement feature of a delivery device to transfer rotational motion from a rotatable shaft of the delivery device to the implantable device 10.

For example, in the embodiment of FIGS. 16A-16C, the implantable device 10 may include a docking member 30 extending from the proximal end 14 of the housing 12 along a longitudinal axis of the housing 12. The docking member 30 may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may be an enlarged portion relative to the neck portion 34. For example, the head portion 32 may have a radial dimension from the longitudinal axis of the implantable device 10 which is greater than a radial dimension of the neck portion from the longitudinal axis of the implantable device 10.

The head portion 32 may include a recess 82 extending into the head portion 32 from a proximal surface 84 of the head portion 32. The recess 82 may be configured to receive a rotational driving instrument therein. For example, the recess 82 may be configured to receive a distal driver mechanism of a rotational driving instrument therein. In some instances, the recess 82 may extend generally perpendicular to the longitudinal axis of the housing 12. In some embodiments, the recess 82 may extend across the head portion 32 from a first side of the head portion 32 to a second

side of the head portion 32. As shown in FIG. 16C, the head portion 32 may include a distal surface 85 opposite the proximal surface 84 from which the neck portion 34 extends from. In some instances, the recess 82 may extend into the head portion 32 from the proximal surface 84 toward the distal surface 85, but does not extend to the distal surface 85. However, in other embodiments the recess 82 may extend to the distal surface 85.

The head portion 32 may also include a member extending across the recess 82 dividing the recess 82 into a first recess portion 82a on a first side of the member and a second recess portion 82b on a second side of the member. As shown in FIGS. 16A-16C, the member may be a pin 88 extending across the recess 82 or bridging across the recess 82. In some instances, the pin 88 may extend generally perpendicular to the recess 82 and/or the longitudinal axis of the housing 12. The pin 88 may be inserted through a hole 89 in the head portion 32 to position the pin 88 across the recess 82, for example.

A tether 80 may extend through a passage beneath the pin 88 defined by the recess 82 during delivery of the implantable device 10. For example, the tether 80 may be attached to the pin 88 and extend proximally from the pin 88 along an elongate shaft of a delivery device to a location accessible by a physician during implantation of the implantable device 10. Once the implantable device 10 has been properly implanted in the heart H, the tether 80 may be detached from the pin 88 and withdrawn from the patient.

It is noted that in other embodiments the tether 80 may be attached to the docking member 30 (such as through a passage in the docking member 30) and extend proximally from the docking member 30 along an elongate shaft of a delivery device to a location accessible by a physician during implantation of the implantable device 10. Similarly, once the implantable device 10 has been properly implanted in the heart H, the tether 80 may be detached from the docking member 30 and withdrawn from the patient.

An exemplary delivery device 100 including a rotational driving instrument 102 and a delivery sheath 104 is illustrated in FIG. 17A. The rotational driving instrument 102 may include an elongate drive shaft 106 and a driver mechanism 108 at the distal end of the elongate drive shaft 106. The driver mechanism 108 may be configured for engagement with the head portion 32 of the docking member 30 to transfer rotational and/or longitudinal movement therebetween. The rotational driving instrument 102 may extend through a lumen 110 of the delivery sheath 104. The driving instrument 102 may be rotatable and longitudinally movable relative to the delivery sheath 104. The delivery sheath 104 may be sized such that the implantable device 10 may be positioned in a distal region of the lumen 110, with the driving instrument 102 engaged with a proximal portion of the implantable device 10 and extending proximally therefrom.

The driver mechanism 108 may include a pusher 112, such as a plate, located at the distal end of the elongate shaft 106 having a distal end surface 116 configured to engage the proximal surface 84 of the docking member 30. The driver mechanism 108 may also include one or more, or a plurality of protuberances, such as lugs 114, extending distally from the distal end surface 116 of the pusher 112, or otherwise arranged. For example, the driver mechanism 108 shown in FIG. 17A includes a first lug 114 and a second lug 114 spaced from the first lug 114 and extending in a distal direction from the distal end surface 116 of the pusher 112. The lug(s) 114 may be configured to engage in the recess 82 of the head portion 32 of the docking member 30.

The rotational driving instrument **102** may also include a lumen **118** extending therethrough. For example, the lumen **118** may extend through the elongate shaft **106** to an opening in the distal end surface **116** of the pusher **112** of the driver mechanism **108**. The lumen **118** may be configured to receive the tether **80** therethrough such that the tether **80** may extend along the delivery device **100** to a proximal region of the delivery device **100** through the driving instrument **102**. In other instances, the tether **80** may extend along the delivery device **100** through the lumen **110** of the delivery sheath **104** and external of the driving instrument **102**, for example.

FIG. **17B** illustrates an exemplary interaction between the delivery device **100** and the implantable device **10** with the docking member **30** shown in FIGS. **15A-15C** during delivery and implantation of the implantable device **10** in a heart H, or other desired anatomy. As shown in FIG. **17B**, the implantable device **10** may be positioned in the lumen **110** of the delivery sheath **104** with the driving instrument **102** engaged with the docking member **30**. For instance, the distal end surface **116** of the pusher **112** may abut the proximal surface **84** of the head portion **32** of the docking member **30** while the first lug **114** is positioned in the first recess portion **82a** on a first side of the member **86** and the second lug **114** is positioned in the second recess portion **82b** on a second side of the member **86**.

Accordingly, with the driver mechanism **108** engaged to the docking member **30**, rotational movement of the driving instrument **102** may be transferred to the implantable device **10** to screw the helical fixation anchor **90** into a tissue wall and/or unscrew the helical fixation anchor **90** from a tissue wall.

FIG. **17C** illustrates an exemplary interaction between the delivery device **100** and the implantable device **10** with the docking member **30** shown in FIGS. **16A-16C** during delivery and implantation of the implantable device **10** in a heart H, or other desired anatomy. In many respects the interaction may be similar to that described above regarding FIG. **17B**. However, in FIG. **17C**, the member extending across the recess **82** is shown as a pin **88**. Accordingly, when the driver mechanism **108** is engaged to the docking member **30**, the distal end surface **116** of the pusher **112** may abut the proximal surface **84** of the head portion **32** of the docking member **30** while the first lug **114** is positioned in the first recess portion **82a** on a first side of the pin **88** and the second lug **114** is positioned in the second recess portion **82b** on a second side of the pin **88**.

Accordingly, with the driver mechanism **108** engaged to the docking member **30**, rotational movement of the driving instrument **102** may be transferred to the implantable device **10** to screw the helical fixation anchor **90** into a tissue wall and/or unscrew the helical fixation anchor **90** from a tissue wall.

FIGS. **18A-18D** illustrate alternative embodiments of a driver mechanism **108** for a rotational driving instrument **102** configured to mate with a docking member of an implantable device, such as one or more of the docking members **30** of the implantable device **10**, described herein.

The driver mechanism **108** shown in FIGS. **18A-18C** may be similar to the driver mechanism **108** shown in FIGS. **17A-17C**. For example, the rotational driving instrument **102** may include an elongate drive shaft **106** and a driver mechanism **108** at the distal end of the elongate drive shaft **106**. The driver mechanism **108** may be configured for engagement with the head portion **32** of the docking member **30** to transfer rotational and/or longitudinal movement ther-

ebetween. The rotational driving instrument **102** may extend through a lumen **110** of the delivery sheath **104** (shown in FIG. **17A**).

The driver mechanism **108** may include a pusher **112** having a distal end surface **116** configured to engage the proximal surface **84** of the docking member **30** and one or more, or a plurality of protuberances, such as lugs **114**, extending distally from the distal end surface **116** of the pusher **112**. For example, the driver mechanism **108** shown in FIG. **18A** includes four equally spaced apart lugs **114**, the driver mechanism **108** shown in FIG. **18B** includes three equally spaced apart lugs **114**, and the driver mechanism **108** shown in FIG. **18C** includes four equally spaced apart lugs **114** extending in a distal direction from the distal end surface **116** of the pusher **112**. The lug(s) **114** may be configured to extend into openings between adjacent spokes **70** of the docking members **30** described herein, and engage in the spokes **70** of the head portion **32** of the docking member **30** to transfer rotational torque therebetween.

The rotational driving instrument **102** may also include a lumen **118** extending through the elongate shaft **106** configured to receive the tether **80** therethrough such that the tether **80** may extend along the delivery device **100** to a proximal region of the delivery device **100** through the driving instrument **102**. In other instances, the tether **80** may extend along the delivery device **100** through the lumen **110** of the delivery sheath **104** and external of the driving instrument **102**, for example.

The shape, size, quantity and arrangement of the lugs **114** may be chosen to complement and mate with the shape, size, quantity and arrangement of spokes **70** of the docking member **30**. For example, the lugs **114** shown in FIG. **18C**, may be triangular or wedge shaped to fit between adjacent spokes **70** of the docking member **30** shown in FIG. **8A, 9A, 10A** or **14A**. In other instances, the shape of the lugs **114** may be chosen to complement and mate with the spokes **70** shown in FIG. **11A, 12A** or **13A**, for example.

In other instances, as shown in FIG. **18D**, the driver mechanism **108** of the rotational driving instrument **102** may include a socket **120** shaped, sized and configured to mate with the head portion **32** of the docking member **30** to transfer rotational torque therebetween. For example, as shown in FIG. **18D**, the socket **120** may include opposing arcuate edges and opposing flat edges extending between the arcuate edges, configured to complement the shape and size of the docking member **30** shown in FIG. **4A**. The flat edges of the socket **120** may engage the flat sides of the docking member **30** to transfer rotational torque therebetween. It is noted that in some instances, the socket **120** may include a single flat side for engagement with a flat side of the docking member **30**.

In other instances, the socket **120** may have another shape, size and configuration to mate with the head portion **32** of another docking member **30**. For example, the socket **120** may include a complementary shape, size and configuration to the head portion **32** of the docking member **30** shown in FIG. **8A, 9A, 10A, 11A, 12A, 13A** or **14A** such that the head portion **32** of the docking member **30** fits into the socket **120**. The socket **120** may include at least one edge or surface configured to engage a surface of the head portion **32** of the docking member **30** to transfer rotational torque therebetween.

Those skilled in the art will recognize that aspects of the present disclosure may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departure in form and detail may

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be made without departing from the scope and spirit of the present disclosure as described in the appended claims.

What is claimed is:

1. An implantable leadless cardiac pacing device comprising:

a housing having a proximal end and a distal end;
an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue; and

a docking member extending from the proximal end of the housing along a longitudinal axis of the housing, the docking member configured to facilitate retrieval of the implantable leadless cardiac pacing device;

the docking member including a head portion and a neck portion extending between the housing and the head portion;

the head portion having a radial dimension from the longitudinal axis and the neck portion having a radial dimension from the longitudinal axis less than the radial dimension of the head portion;

the head portion including a plurality of radially extending spokes extending radially outward from the longitudinal axis of the housing;

wherein each spoke includes a base portion proximate the longitudinal axis of the housing and a free end extending radially outward from the base portion, wherein a width of each spoke increases from the base portion toward the free end of the spoke.

2. The implantable leadless cardiac pacing device of claim 1, wherein each of the spokes extends at an oblique angle to the longitudinal axis of the housing toward the distal end such that the free ends of the plurality of spokes are positioned closer to the distal end of the housing than the base portion of the spokes proximate the longitudinal axis of the housing.

3. The implantable leadless cardiac pacing device of claim 1, wherein the plurality of spokes are configured to mate with an engagement mechanism of a rotational driving instrument to transfer rotational torque to the implantable leadless cardiac pacing device.

4. An implantable leadless cardiac pacing device comprising:

a housing having a proximal end and a distal end;
an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue; and

a docking member extending from the proximal end of the housing along a longitudinal axis of the housing, the docking member configured to facilitate retrieval of the implantable leadless cardiac pacing device;

the docking member including a head portion and a neck portion extending between the housing and the head portion;

the head portion having a radial dimension from the longitudinal axis and the neck portion having a radial dimension from the longitudinal axis less than the radial dimension of the head portion;

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the head portion including a plurality of radially extending spokes extending radially outward from the longitudinal axis of the housing;

wherein each of the spokes includes a body portion extending radially outward to a free end of the spoke and a crossing member extending transverse to the body portion.

5. The implantable leadless cardiac pacing device of claim 4, wherein the crossing member extends in opposite directions from the body portion.

6. The implantable leadless cardiac pacing device of claim 5, wherein the spoke is T-shaped.

7. The implantable leadless cardiac pacing device of claim 5, wherein each spoke includes undercut portions at a junction between the crossing member and the body portion of the spoke.

8. A system for retrieving an implantable leadless cardiac pacing device, comprising:

an implantable cardiac pacing device having a housing having a longitudinal axis, an electrode positioned proximate a distal end of the housing, and a docking member extending from a proximal end of the housing opposite the distal end, the docking member including a head portion and a neck portion extending between the housing and the head portion, the head portion including a plurality of radially extending spokes extending radially outward from the longitudinal axis of the housing; and

a retrieval device including a snare having an elongate shaft and one or more loops at a distal end of the elongate shaft;

wherein the one or more loops of the retrieval device are capable of encircling one or more of the radially extending spokes to capture the docking member with the snare;

wherein each spoke includes:

i) a base portion proximate the longitudinal axis of the housing and a free end extending radially outward from the base portion, wherein a width of each spoke increases from the base portion toward the free end of the spoke; or

ii) a body portion extending radially outward to a free end of the spoke and a crossing member extending transverse to the body portion.

9. The system of claim 8, wherein if the spoke includes ii), the crossing member extends in opposite directions from the body portion.

10. The system of claim 9, wherein the spoke is T-shaped.

11. The system of claim 9, wherein each spoke includes undercut portions at a junction between the crossing member and the body portion of the spoke.

12. The system of claim 8, wherein if the spoke includes i), each of the spokes extends at an oblique angle to the longitudinal axis of the housing toward the distal end such that the free ends of the plurality of spokes are positioned closer to the distal end of the housing than the base portion of the spokes proximate the longitudinal axis of the housing.

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